

STIC Search Report

STIC Database Tracking Number: 134

TO: Andrea Ragonese Location: pk1 11e50

Art Unit: 3743

Tuesday, October 12, 2004

Case Serial Number: 10/079604

From: Emory Damron Location: EIC 3700

CP2-2C08

Phone: 305-8587

Emory.Damron@uspto.gov

Search Notes

Dear Andrea,

Please find below an inventor search in the bibliographic and full-text foreign patent files, as well as keyword searches in the patent and non-patent literature files, both bibliographic and full text.

References of potential pertinence have not been tagged (per your request), so please review all the packets carefully.

Please note any manual highlighting which I've done within the document.

In addition to searching on Dialog, I also searched EPO/JPO/Derwent.

Please contact me if I can refocus or expand any aspect of this case, and please take a moment to provide any feedback (on the form provided) so EIC 3700 may better serve your needs.

Sincerely,

Emory Damron

Technical Information Specialist

EIC 3700, US Patent & Trademark Office

Phone: (703) 305-8587/ Fax: (703) 306-5915

Emory.damron@uspto.gov



SEARCH REQUEST FORM

Scientific and Technical Information Center
Requester's Full Name: ANDREA MAGO~SSE Examiner #: 77465 Date: 10/1/2004 Art Unit: 3743 Phone Number 306 - 4055 Serial Number: 10 079 604 Mail Box and Bldg/Room Location: K1 // E56 Results Format Preferred (circle): PAPER DISK E-MAIL
If more than one search is submitted, please prioritize searches in order of need.
Please provide a detailed statement of the search topic, and describe as specifically as possible the subject matter to be searched. Include the elected species or structures, keywords, synonyms, acronyms, and registry numbers, and combine with the concept or utility of the invention. Define any terms that may have a special meaning. Give examples or relevant citations, authors, etc., if known. Please attach a copy of the cover sheet, pertinent claims, and abstract.
Title of Invention: ((FARING MODES OF OPERATION OF MED) (ALSNGINE) WILL'S
Title of Invention: ((EARING MODES OF OPERATION OF MEDICAL ENGINEERING) WILLS Inventors (please provide full names): KRUGER, THOMAS; SCHMIDT, HARTMUT; WAHLE, HANS-GEORG Earliest Priority Filing Date: 1 A PRIL 200/
Earliest Priority Filing Date: 1 A PAIL 200/
For Sequence Searches Only Please include all pertinent information (parent, child, divisional, or issued patent numbers) along with the appropriate serial number.
Dec attacked
STAFF USE ONLY Searcher: Merical Date Phone #: 305 858 AA Sequence (#) STN Searcher Phone #: 305 858 AA Sequence (#) Dialog Market Searcher Location:

Set Įtems Description AU=(KRUGER T? OR KRUGER, T? OR SCHMIDT H? OR SCHMIDT, H? OR S1 2658 WAHLE H? OR WAHLE, H? OR WAHLE G? OR WAHLE, G?) S2 (TOM OR THOMAS) (2N) KRUGER OR HARTMUT (2N) SCHMIDT OR (HANS OR GEORG?) (2N) WAHLE S3 151804 RESPIR? OR BREATH? OR VENTILAT? OR BREATH? OR CPAP OR PEEP OR IPAP S4 471282 IC=(A62B? OR A61M? OR F16K? OR A61B?) S5 108 S1:S2 AND S3:S4 S6 31 S5 AND S3 31 S7 IDPAT (sorted in duplicate/non-duplicate order) ? show files File 347: JAPIO Nov 1976-2004/Jun (Updated 041004) (c) 2004 JPO & JAPIO File 350: Derwent WPIX 1963-2004/UD, UM &UP=200464 (c) 2004 Thomson Derwent

INVENTOR ANTHOR
SEARCH
PATLIT &
NON PATLIT
SEIECTED
SOUTER MITS

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APPLICATION
            (Item 10 from file: 350)
7/3,K/10
DIALOG(R)File 350:Derwent WPIX
(c) 2004 Thomson Derwent. All rts. reserv.
015031046
             **Image available**
WPI Acc No: 2003-091563/200308
XRPX Acc No: N03-072498
   Respirator operation mode clearance method involves determining
  clearance of available respiration modes on respirator , based on data
  read from chip card by writing/reading unit
Patent Assignee: DRAEGER MEDICAL & CO AG KGAA (DRAE-N); DRAGER MEDICAL & CO
  AG KGAA (DRAG-N); KRUGER T (KRUG-I); SCHMIDT H (SCHM-I); WAHLE H (WAHL-I)
Inventor: KRUEGER T; SCHMIDT H ; WAHLE H ; KRUGER T ; WAHLE H G
Number of Countries: 003 Number of Patents: 003
Patent Family:
Patent No
             Kind
                    Date
                            Applicat No
                                           Kind
                                                  Date
                                                           Week
US 20020144682 A1 20021010 US 200279604
                                            Α
                                                 20020220 200308
FR 2823121 A1 20021011 FR 20024149
                                            Α
                                                20020403 200308
DE 10116650
             A1 20021107 DE 1016650
                                            Α
                                                20010404 200308
Priority Applications (No Type Date): DE 1016650 A 20010404
Patent Details:
Patent No Kind Lan Pg
                       Main IPC
                                    Filing Notes
                     7 A62B-007/00
US 20020144682 A1
FR 2823121
                      A61M-016/00
             Α1
DE 10116650
             Α1
                      A61B-019/00
   Respirator operation mode clearance method involves determining
  clearance of available respiration modes on respirator , based on data
  read from chip card by writing/reading unit
... Inventor: SCHMIDT H ...
... WAHLE H ...
... KRUGER T ...
... WAHLE H G
Abstract (Basic):
           The data specifying different available respiration modes on
    the respirator, are read from a chip card (2) by a writing/reading
    unit (3). The cleaning of the respiration modes is determined, based
    on the data read by the writing/reading unit.
          An INDEPENDENT CLAIM is included for respirator system...
... For cleaning mode of operations such as intermittent mandatory
    ventilation (IMV), continuous positive airway pressure ( CPAP ) and
    high-frequency ventilation (HFV) on respirator .
... Enables the respiration modes on the respirator to be changed
    without great technical effort...
... The figure shows a schematic view of the respirator .
Title Terms: RESPIRATION;
International Patent Class (Main): A61B-019/00 ...
... A61M-016/00 ...
... A62B-007/00
```

7/3,K/27 (Item 27 from file: 350)

DIALOG(R) File 350: Derwent WPIX

(c) 2004 Thomson Derwent. All rts. reserv.

004068431

WPI Acc No: 1984-213972/198435

XRPX Acc No: N84-160199

Dry cold air stream producer - has liquid nitrogen source which mixes

with filtered air flow

Patent Assignee: MESSER GRIESHEIM GMBH (MESG)

Inventor: JANKOWSKI D; SCHMIDT H ; THOMA K; VOLKER W; VONDERBEY T

Number of Countries: 009 Number of Patents: 006

Patent Family:

Patent No	Kind	Date	Applicat No	Kind	·Date	Week	
DE 3305434	Α	19840823	DE 3305434	Α	19830217	198435	В
EP 116834	Α	19840829	EP 84100220	Α	19840111	198435	
NO 8400333	Α	19840910				198443	
US 4532779	А	19850806	US 84573838	Α	19840125	198534	
DE 3305434	С	19851128				198549	
EP 116834	В	19860528				198622	

Priority Applications (No Type Date): DE 3305434 A 19830217

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

DE 3305434 A 10

EP 116834 A G

Designated States (Regional): AT BE FR GB NL SE

EP 116834 B G

Designated States (Regional): AT BE FR GB NL SE

...Inventor: SCHMIDT H

...Abstract (Basic): are attached. A temp. sensor (21) is located near the hand piece. A spent air **ventilator** (22) is situated near by which runs while the machine is switched on. An oxygen...

per feverall

```
Items
Set
                Description
                (VENTILAT? OR RESPIRAT? OR BREATH?) (3N) (DEVICE? OR UTENSIL?
        16723
S1
              OR APPARAT? OR TOOL? OR IMPLEMENT? OR INSTRUMENT? OR APPLIAN-
             C? OR EQUIPMENT? OR MACHINE? OR MECHANIC?)
S2
               VENTILATOR? OR VENTILATER? OR RESPIRATOR? OR RESPIRATER? OR
              HFV OR IMV OR IPAP OR CPAV OR PEEP OR CPAP
S3
      1930912
                CLEAR? OR CANCEL? OR ERASE? OR ERASUR? OR ERASING? OR DELE-
             T? OR OVERRID? OR OVERWRIT? OR OVER() (RIDE? OR RIDING OR WRIT-
             ?) OR REPROGRAM? OR REMOV?
S4
      6047087
                OPERAT? OR FUNCTION? OR PERFORMANC? OR WORKING? OR EXECUTI?
              OR DATA? OR PROGRAM?
                (READ? OR SCAN? OR DECOD?) (5N) (WRIT? OR CODE? OR CODING? OR
S5
       152811
              CODIF?)
S6
                 (CHIP? OR SMART? OR DEBIT? OR PROGRAMABL?) -
        11821
             (3N) CARD? OR SMARTCARD? OR CHIPCARD?
S7
       268323
               (STORE? OR STORING? OR STORAGE) (3N) (DEVICE? OR MEDIUM? OR -
             ELECTRONIC? OR OPTIC? OR MAGNET?)
S8
      1019446 CACHE? OR MEMORY? OR RAM OR (EXTERNAL OR REMOVABL? OR DETA-
             CHABL? OR STANDALONE OR STAND() ALONE OR PORTABL OR INSERTABL?-
             )(2N)(UNIT? OR DEVICE?)
       809193 CPU OR CPUS OR PROGRAM?()CONTROL? OR PROCESS?(2N)CONTROL? -
S9
             OR MICROPROCESS? OR DATAPROCESS? OR CENTRALPROCESS? OR (MICRO
             OR DATA OR CENTRAL) () PROCESS?
S10
       251554 PROCESS?()UNIT? OR WORKSTATION? OR WORK()STATION? OR DESKT-
             OP? OR DESK() (TOP OR TOPS) OR SERVER?
S11
       785241
                COMPUTER OR COMPUTERS OR PC OR PCS
S12
      4273140
                METHOD? ?
S13
                SYSTEM? ?
      3086734
S14
      2498531
                PROCESS??
       204660 PROCEDUR?
227816 TECHNIQU?
493577 MODE? ?
S15
S16
S17
       471282 IC=(A62B? OR A
9383 S1:S2 AND S18
S18
                IC=(A62B? OR A61M? OR F16K? OR A61B?)
S19
        52418 S19 OR S1:S2
S20
         2043 S20 AND S6:S8
S21
S22
                S20 AND S9:S11
         1954
S23
          257
                S21 AND S22
         3740 S21:S22
S24
S25
           74
                S24 AND S3(5N)S4:S8
S26
           4
                S23 AND S25
          74
S27
                S25:S26
S28
          201
                S23 AND S12:S17
S29
          74
                S28 AND S18
S30
          147
                S27 OR S29
S31
          147
                IDPAT (sorted in duplicate/non-duplicate order)
? show files
File 347: JAPIO Nov 1976-2004/Jun (Updated 041004)
         (c) 2004 JPO & JAPIO
File 350: Derwent WPIX 1963-2004/UD, UM & UP=200464
         (c) 2004 Thomson Derwent
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31/3, K/12
              (Item 12 from file: 350)
DIALOG(R) File 350: Derwent WPIX
(c) 2004 Thomson Derwent. All rts. reserv.
016309417
             **Image available**
WPI Acc No: 2004-467312/200444
Related WPI Acc No: 1994-134983; 1995-383132; 1996-496747; 1997-525383;
  1998-168289; 1998-251468; 1998-426808; 1998-456711; 1998-568188;
  1999-228839; 1999-242495; 1999-287122; 1999-302397; 1999-311681;
  1999-384097; 1999-405126; 1999-417667; 1999-507606; 1999-526845;
  1999-539738; 1999-561252; 2000-012778; 2000-061786; 2000-181692;
  2000-195149; 2000-328448; 2000-338806; 2000-338807; 2000-338954;
  2000-423081; 2000-431044; 2000-474547; 2000-498702; 2000-571401;
  2000-593531; 2000-655125; 2001-210131; 2001-225710; 2001-307032;
  2001-307130; 2001-407641; 2001-513222; 2001-564621; 2001-578438;
  2001-579931; 2001-611417; 2001-624850; 2002-112617; 2002-121382;
  2002-170531; 2002-215991; 2002-327599; 2002-360451; 2002-415808;
  2002-416321; 2002-433601; 2002-453253; 2002-470164; 2002-527573;
  2002-617729; 2003-074907; 2003-657592; 2004-009535; 2004-131367;
  2004-202085; 2004-460441; 2004-467342; 2004-498375; 2004-498376;
  2004-498377
XRPX Acc No: N04-369203
  Airflow monitoring system for chronic respiratory affliction, has
  health care professional computer that is in signal communication with
  clearing house receives health-related information based on
  airflow-related data
Patent Assignee: HEALTH HERO NETWORK INC (HEAL-N)
Inventor: BROWN S J
Number of Countries: 001 Number of Patents: 001
Patent Family:
Patent No
              Kind
                     Date
                             Applicat No
                                            Kind
                                                   Date
                                                             Week
US 20040106855 A1
                    20040603 US 92977323
                                             Α
                                                  19921117
                                                             200444
                             US 94233397
                                             Α
                                                  19940426
                             US 95481925
                                             Α
                                                 19950607
                             US 99237194
                                             Α
                                                 19990126 -
                             US 2003605547
                                                 20031007
                                             Α
Priority Applications (No Type Date): US 92977323 A 19921117; US 94233397 A
  19940426; US 95481925 A 19950607; US 99237194 A 19990126; US 2003605547 A
  20031007
Patent Details:
Patent No Kind Lan Pg
                         Main IPC
                                      Filing Notes
US 20040106855 A1
                     21 G06F-017/60
                                      Cont of application US 92977323
                                     Cont of application US 94233397
                                     Cont of application US 95481925
                                     Cont of application US 99237194
                                     Cont of patent US 5307263
                                     Cont of patent US 5899855
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Airflow monitoring system for chronic respiratory affliction, has health care professional computer that is in signal communication with clearing house receives health-related information based on airflow...

Abstract (Basic):

The system has a clearing house (54) that receives and communicates data. A microprocessor -based unit (12) with a microprocessor, display and a memory is arranged to communicate airflow related data to the server. A health care professional computer in signal communication with the house receives health-related information based on the airflow-related...

... An INDEPENDENT CLAIM is also included for an airflow monitoring ${\tt method}$.

. . .

- ... Used for self-care monitoring and control of afflictions and physical conditions e.g. chronic **respiratory** afflictions...
- ... The **system** enables healthcare professional to review the data and record it for latter user to perform...
- ...The drawing shows a block diagram depicting a healthcare monitoring system .

... Microprocessor -based unit (12

... Title Terms: SYSTEM;

International Patent Class (Additional): A61B-005/00

31/3,K/37 (Item 37 from file: 350) DIALOG(R) File 350: Derwent WPIX (c) 2004 Thomson Derwent. All rts. reserv. 015161090 **Image available** WPI Acc No: 2003-221618/200321 XRAM Acc No: C03-056389 XRPX Acc No: N03-176785 General purpose modular sensor unit for portable health monitor, comprises application software for controlling intelligent processor and control layer which processes data output from sensor array layer Patent Assignee: BATTELLE MEMORIAL INST (BATT); GRIFFIN J W (GRIF-I); LIND M A (LIND-I); MORGAN G B (MORG-I); PRIDDY K L (PRID-I); RIDGWAY R W (RIDG-I); STEIN S L (STEI-I) Inventor: GRIFFIN J W; LIND M A; MORGAN G B; PRIDDY K L; RIDGWAY R W; STEIN Number of Countries: 101 Number of Patents: 004 Patent Family: Patent No Kind Date Applicat No Kind Date Week WO 200304975 A1 20030116 WO 2002US20908 A 20020702 200321 US 20030033032 A1 20030213 US 2001302563 P 20010702 200321 US 2002188469 Α 20020702 EP 1405044 20040407 Α1 EP 2002742377 Α 20020702 200425 WO 2002US20908 Α 20020702 AU 2002315514 A1 20030121 AU 2002315514 20020702 Α 200452 Priority Applications (No Type Date): US 2001302563 P 20010702; US 2002188469 A 20020702 Patent Details: Patent No Kind Lan Pg Main IPC Filing Notes WO 200304975 A1 E 51 G01D-021/02 Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ OM PH PL PT RO RU SD SE SG SI SK SL TJ TM TN TR TT TZ UA UG US UZ VN YU ZA ZM ZW Designated States (Regional): AT BE BG CH CY CZ DE DK EA EE ES FI FR GB GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SK SL SZ TR TZ UG ZM ZW US 20030033032 A1 G05B-011/01 Provisional application US 2001302563 EP 1405044 A1 E G01D-021/02 Based on patent WO 200304975 Designated States (Regional): AL AT BE BG CH CY CZ DE DK EE ES FI FR GB

GR IE IT LI LT LU LV MC MK NL PT RO SE SI SK TR AU 2002315514 A1 G01D-021/02 Based on patent WO 200304975

General purpose modular sensor unit for portable health monitor, comprises application software for controlling intelligent processor and control layer which processes data output from sensor array layer

Abstract (Basic):

- The general purpose intelligent processor and control layers comprises reprogrammable memory which stores application specific software to control the operation of these layers, which process conditioned...
- ...output from sensor array layer. A power layer supplies power to the sensor array layer, processor and control layers. The processor power, array and control layers are arranged to form a sensor module. medicine, biological threat detection and/or non-invasive blood chemistry testing, drug efficacy monitoring, medical ventilator

monitoring, crop health monitor and/or smart patch medical emergency diagnostics, etc...

31/3,K/38 (Item 38 from file: 350) DIALOG(R) File 350: Derwent WPIX (c) 2004 Thomson Derwent. All rts. reserv. 015150236 **Image available** WPI Acc No: 2003-210763/200320 XRPX Acc No: N03-167919 Ventilator has embedded web server which can be connected to external monitoring devices and can be operated from mains power or external battery Patent Assignee: EVENT MEDICAL LTD (EVEN-N); IMT MEDICAL AG (IMTM-N) Inventor: DASCHER J; GRIFFITHS M; DAESCHER J Number of Countries: 097 Number of Patents: 003 Patent Family: Patent No Kind Date Applicat No Kind Date Week WO 200313635 20030220 200320 B Α1 WO 2001IB1362 Α 20010730 EP 1414509 A1 20040506 EP 2001956725 Α 20010730 200430 WO 2001IB1362 Α 20010730 AU 2001278642 A1 20030224 AU 2001278642 Α 20010730 200460 WO 2001IB1362 Α 20010730 Priority Applications (No Type Date): WO 2001IB1362 A 20010730 Patent Details: Patent No Kind Lan Pg Main IPC Filing Notes WO 200313635 A1 E 14 A61M-016/00 Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EC EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SL SZ TR TZ UG ZW EP 1414509 A1 E A61M-016/00 Based on patent WO 200313635 Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI TR Based on patent WO 200313635 AU 2001278642 A1 A61M-016/00 Ventilator has embedded web server which can be connected to external monitoring devices and can be operated from mains power or external battery Abstract (Basic): The ventilator has a housing (7) with gas connections (1). There is a controlled valve (2), a... ...compressor (6) and at least one patient connection (12). At least one of the control systems (2,4 or 8) is connected to an embedded web server (5) which provides a connection to one external monitor (13) via at least one data...

Control systems

International Patent Class (Main): A61M-016/00

(4,8...

APPLICAMEN DIALOG(R) File 350: Derwent WPIX (c) 2004 Thomson Derwent. All rts. reserv. 015031046 **Image available** WPI Acc No: 2003-091563/200308 XRPX Acc No: N03-072498 Respirator operation mode clearance method involves determining clearance of available respiration modes on respirator , based on data read from chip card by writing/reading unit Patent Assignee: DRAEGER MEDICAL & CO AG KGAA (DRAE-N); DRAGER MEDICAL & CO AG KGAA (DRAG-N); KRUGER T (KRUG-I); SCHMIDT H (SCHM-I); WAHLE H (WAHL-I) Inventor: KRUEGER T; SCHMIDT H; WAHLE H; KRUGER T; WAHLE H G Number of Countries: 003 Number of Patents: 003 Patent Family: Patent No Kind Date Applicat No Kind Date Week US 20020144682 A1 20021010 US 200279604 Α 20020220 200308 B FR 2823121 Al 20021011 FR 20024149 Α 20020403 200308 DE 10116650 A1 20021107 DE 1016650 Α 20010404 200308 Priority Applications (No Type Date): DE 1016650 A 20010404 Patent Details: Patent No Kind Lan Pg Main IPC Filing Notes US 20020144682 A1 7 A62B-007/00 FR 2823121 A61M-016/00 A1 A1 DE 10116650 A61B-019/00 Respirator operation mode clearance method involves determining clearance of available respiration modes on respirator , based on data read from chip card by writing/reading unit Abstract (Basic): The data specifying different available respiration modes on the respirator, are read from a chip card (2) by a writing/reading unit (3). The cleaning of the respiration modes is determined... An INDEPENDENT CLAIM is included for respirator system... ... For cleaning mode of operations such as intermittent mandatory ventilation (IMV), continuous positive airway pressure (CPAP) and high-frequency ventilation (HFV) on respirator Enables the respiration modes on the respirator to be changed without great technical effort... ... The figure shows a schematic view of the respirator Chip card (2 International Patent Class (Main): A61B-019/00 A61M-016/00 ...

31/3,K/40

... A62B-007/00

(Item 40 from file: 350)

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31/3,K/49
              (Item 49 from file: 350)
DIALOG(R) File 350: Derwent WPIX
(c) 2004 Thomson Derwent. All rts. reserv.
             **Image available**
014573514
WPI Acc No: 2002-394218/200242
XRPX Acc No: N02-309083
  Breathing gas delivery system has microprocessor calculating excess
  leak, tidal profile and peak flow using measured flow rate and purge hole
  leak profile
Patent Assignee: MALLINCKRODT INC (MLCW )
Inventor: BONNETTE B J; EMERSON P F; HANSEN G L
Number of Countries: 029 Number of Patents: 004
Patent Family:
Patent No
              Kind
                     Date
                             Applicat No
                                            Kind
                                                   Date
                                                            Week
                             WO 2001US30456 A
WO 200226304
              A2
                   20020404
                                                 20010928
                                                           200242
US 6546930
               В1
                   20030415
                             US 2000672955
                                             Α
                                                 20000929
                                                           200329
EP 1322368
               A2
                  20030702
                             EP 2001979321
                                             Α
                                                 20010928
                                                           200344
                             WO 2001US30456 A
                                                 20010928
JP 2004509710 W
                   20040402
                             WO 2001US30456 A
                                                 20010928
                                                           200424
                             JP 2002530133
                                             A
                                                 20010928
Priority Applications (No Type Date): US 2000672955 A 20000929
Patent Details:
Patent No Kind Lan Pg
                         Main IPC
                                     Filing Notes
WO 200226304 A2 E 26 A61M-016/00
   Designated States (National): CA JP
   Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LU
   MC NL PT SE TR
US 6546930
                       A61M-016/00
              В1
EP 1322368
              A2 E
                       A61M-016/00
                                     Based on patent WO 200226304
   Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT
   LI LT LU LV MC MK NL PT RO SE SI TR
JP 2004509710 W
                    71 A61M-016/00
                                     Based on patent WO 200226304
  Breathing gas delivery system has microprocessor calculating excess
  leak, tidal profile and peak flow using measured flow rate and purge hole
Abstract (Basic):
            System comprises a blower with a gas flow rate sensor and a
    memory containing purge hole leak profiles corresponding to specific
    types of breathing appliances . A microprocessor calculates excess
    leak, tidal volume and peak flow using the measured flow rate and the
           There is an INDEPENDENT CLAIM for a method of delivering a
    breathing gas to a patient...
... System is for use in treating sleep apnea...
... The figure shows the breathing gas delivery system .
... Title Terms: SYSTEM;
International Patent Class (Main): A61M-016/00
International Patent Class (Additional): A62B-007/00 ...
```

... F16K-031/02

31/3,K/50 (Item 50 from file: 350) DIALOG(R) File 350: Derwent WPIX (c) 2004 Thomson Derwent. All rts. reserv. 014496531 **Image available** WPI Acc No: 2002-317234/200236 XRPX Acc No: N02-248371 User interface for use with medical apparatus e.g. medical ventilator , has controller to process normal and signal data and show signal data as sector in regular polygon on display screen Patent Assignee: SIEMENS-ELEMA AB (SIEI) Inventor: MALMBORG J Number of Countries: 028 Number of Patents: 003 Patent Family: Applicat No Patent No Kind Date Kind Date 20010612 200236 B EP 1178288 A1 20020206 EP 2001114238 Α US 20020015034 A1 20020207 US 2001919105 Α 20010731 200236 20020528 JP 2001234104 JP 2002153429 A Α 20010801 200238 Priority Applications (No Type Date): SE 20002806 A 20000801 Patent Details: Patent No Kind Lan Pg Main IPC Filing Notes EP 1178288 A1 E 13 G01D-007/02 Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI TR US 20020015034 A1 G09G-005/00 JP 2002153429 A 9 A61B-005/00 User interface for use with medical apparatus e.g. medical ventilator , has controller to process normal and signal data and show signal data as sector in regular polygon on display ... Abstract (Basic): A controller (18) processes normal data for two or more parameters, as well as the signal data for the... An input unit (20) introduces the signal data into the controller. A memory (14) stores the normal data. The regular polygon corresponds to the representation... ...For displaying physiological or apparatus-related parameters, and for use with medical apparatus e.g. medical ventilator Memory (14 ... Title Terms: PROCESS ; International Patent Class (Main): A61B-005/00 ... International Patent Class (Additional): A61B-005/02 ...'

... A61M-016/00

DIALOG(R) File 350: Derwent WPIX (c) 2004 Thomson Derwent. All rts. reserv. 014127175 **Image available** WPI Acc No: 2001-611385/200170 XRAM Acc No: C01-182649 XRPX Acc No: N01-456382 Dry powder inhaler for nasal and/or oral respiratory delivery of dry powder-based drug formulations, is provided with control system comprising controller, power source, transformer, and computer -readable program code Patent Assignee: UNIV NORTH CAROLINA (UYNC-N); CROWDER T M (CROW-I); HICKEY A J (HICK-I) Inventor: CROWDER T M; HICKEY A J Number of Countries: 095 Number of Patents: 010 Patent Family: Patent No Kind Date Applicat No Kind Date Week WO 200168169 Α1 20010920 WO 2001US2262 20010124 200170 Α AU 200131102 Α 20010924 AU 200131102 Α 20010124 200208 NO 200204311 Α 20021111 WO 2001US2262 Α 20010124 200304 NO 20024311 Α 20020909 EP 1267969 A1 20030102 EP 2001903260 20010124 Α 200310 WO 2001US2262 20010124 Α KR 2002086624 Α 20021118 KR 2002711799 Α 20020909 200320 BR 200109127 Α 20030422 BR 20019127 Α 20010124 200330 WO 2001US2262 Α 20010124 CN 1416357 Α 20030507 CN 2001806260 Α 20010124 200353 JP 2003526480 W 20030909 JP 2001566730 Α 20010124 200360 WO 2001US2262 20010124 Α MX 2002008605 A1 20030501 WO 2001US2262 Α 20010124 200415 MX 20028605 Α 20020903 US 20040123864 A1 WO 2001US2262 20040701 Α 20010124 200444 US 2003204609 Α 20030129 Priority Applications (No Type Date): US 2000188543 P 20000310; US 2003204609 A 20030129 Patent Details: Patent No Kind Lan Pg Main IPC Filing Notes WO 200168169 A1 E 71 A61M-015/00 Designated States (National): AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW Designated States (Regional): AT BE CH CY DE DK EA ES FI FR GB GH GM GR IE IT KE LS LU MC MW MZ NL OA PT SD SE SL SZ TR TZ UG ZW AU 200131102 A A61M-015/00 Based on patent WO 200168169 NO 200204311 A61M-000/00 Α EP 1267969 Al E A61M-015/00 Based on patent WO 200168169 Designated States (Regional): AL AT BE CH CY DE DK ES FI FR GB GR IE IT LI LT LU LV MC MK NL PT RO SE SI TR KR 2002086624 A A61M-015/00 BR 200109127 Α A61M-015/00 Based on patent WO 200168169 CN 1416357 А A61M-015/00 JP 2003526480 W 72 A61M-015/00 Based on patent WO 200168169 MX 2002008605 A1 A61M-015/00 Based on patent WO 200168169 US 20040123864 A1 A61M-015/00 Dry powder inhaler for nasal and/or oral respiratory delivery of dry powder-based drug formulations, is provided with control system comprising controller, power source, transformer, and computer -readable

31/3, K/55

(Item 55 from file: 350)

program code

Abstract (Basic):

- A dry powder inhaler having an active energy-assisted dispersing system is constructed with a housing for receiving a multi-dose dry powder package; and a control system positioned in the housing and comprising a controller, a power source, a transformer, and a computer -readable program code.
- A dry powder inhaler (10) having an active energy-assisted dispersing system, is provided with a control system and a housing. The housing receives a multi-dose dry powder package and includes an airstream exit flow path. The control system is positioned in the housing and comprises a controller, a power source, a transformer, and a computer -readable program code. The power source generates excitation energy directed to a selected region of...
- ...B) a **method** of dispersing a predetermined quantity of dry powder pharmaceutical drug to a patient's airstream...
- ...C) a **method** of controlling the dry powder inhaler...
- ...D) a method of fabricating a multi-dose dry powder package; and...
- ...E) a **computer** program product for directing the operation of the dry powder inhaler...
- ...administration of the dry powder drug and adjusting the energy directed to the active delivery system. The computer program product comprises a computer -readable storage medium having computer '-readable program code embodied in the medium. The computer -readable program code includes program codes for respectively...
- ...ii) defining a fuzzy logic analysis model to control the amount of energy delivered to the active delivery system;
- ...the type, frequency, and/or size of the excitation signal directed to the active energy system of the inhaler...
- ...For nasal and/or oral **respiratory** delivery of dry powder-based drug formulations
 Technology Focus:
- a disposable multi-dose dry powder package having spatially-separated dry powder drug doses. The lcomputer -readable program code establishes a fuzzy logic model of the flowability of the dry powder formulation, which is administered, and an associated excitation...
- ... Title Terms: SYSTEM;

International Patent Class (Main): A61M-000/00 ...

... A61M-015/00

International Patent Class (Additional): A61M-013/00

(Item 60 from file: 350) 31/3, K/60DIALOG(R) File 350: Derwent WPIX (c) 2004 Thomson Derwent. All rts. reserv. 013684080 **Image available** WPI Acc No: 2001-168304/200117 XRAM Acc No: C01-050171 XRPX Acc No: N01-121406 Ventilator comprises ventilator setting control(s), sensors, a processing subsystem, and a feedback system responsive to the response signal of the processing subsystem Patent Assignee: UNIV FLORIDA (UYFL); BANNER M J (BANN-I); BLANCH P B (BLAN-I); EULIANO N R (EULI-I); PRINCIPE J C (PRIN-I) Inventor: BANNER M J; BLANCH P B; EULIANO N R; PRINCIPE J C Number of Countries: 022 Number of Patents: 003 Patent Family: Patent No Kind Date Applicat No Kind Date Week WO 200100265 20010104 A1 WO 2000US18195 A 20000630 200117 B AU 200060645 Α 20010131 AU 200060645 20000630 Α 200124 US 20040003813 A1 20040108 US 99141676 Р 19990630 200404 US 2000607713 20000630 Α US 2003407160 Α 20030404 Priority Applications (No Type Date): US 99141676 P 19990630; US 2000607713 A 20000630; US 2003407160 A 20030404 Patent Details: Patent No Kind Lan Pg Main IPC Filing Notes WO 200100265 A1 E 55 A61M-016/00 Designated States (National): AU CA JP Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE AU 200060645 A Based on patent WO 200100265 US 20040003813 A1 A61M-016/00 Provisional application US 99141676

Cont of application US 2000607713

Ventilator comprises ventilator setting control(s), sensors, a processing subsystem, and a feedback system responsive to the response signal of the processing subsystem

Abstract (Basic):

- ... A ventilator comprises ventilator setting control(s); sensors for measuring ventilation support parameters; a processing subsystem connected to receive the output signals from the sensors and the ventilator setting parameter signal from the ventilator setting control; and a feed back system responsive to the response signal of the processing subsystem.
 - A ventilator (20) comprises ventilator setting control(s); sensors (52) for measuring ventilation support parameters; a processing subsystem connected to receive the output signals from the sensors and the ventilator setting parameter signal from the ventilator setting control; and a feed back system responsive to the response signal of the processing subsystem. The ventilator setting control governs the supply of ventilation support from the ventilator to the patient via the breathing circuit. Each setting control is selectable to a level setting. Each ventilator setting control generates a ventilator setting parameter signal indicative of the current level setting of the ventilator setting control. The sensors measure ventilation support parameters. Each sensor is connected to a patient...

...an output signal based on the measured ventilation support parameter.

The processing subsystem has a processor and a memory. The processor runs under control of a program stored in the memory. It has an intelligence system that determines a desired level setting of at least one ventilator setting control in response to the ventilator setting parameter signal and the output signals. It generates a response signal based on the determination. The feedback system adjusts at least one of the level settings of the ventilator setting controls of the ventilator.

- ...An INDEPENDENT CLAIM is also included for a **method** of controlling pulmonary ventilation for a **ventilator** comprising...
- ...a) receiving at least one **ventilator** setting parameter signal indicative of the level setting of one **ventilator** setting control...
- ...c) controlling the level settings of the **ventilator** setting controls in response to the received **ventilator** setting parameter signal and the output signals...
- ...in fluid communication with at least one lung of a patient for treating patients with **respiratory** failure...
- ...breathing load expended by the patient (a) to avoid unnecessary medical complications of the required respiratory support; (b) to prevent further damage to a weakened patient; or (c) if it is beyond the capacity or capability of small or disabled patients. The ventilator delivers the most appropriate mode and intra-mode, the most appropriate quality and quantity of ventilation support required by the patient's current physiological needs by (i) receiving ventilator support signals indicative of the sufficiency of ventilation support received by the patient; (ii) receiving at least one ventilator signal indicative of the level settings of the ventilator setting controls of the ventilator; and (iii) determining the desired level settings of the appropriate quality and quantity of ventilation support to the patient...
- \dots The figure shows a block diagram of the ${f ventilator}$ monitor ${f system}$.

... **Ventilator** (20 Technology Focus:

i) arterial blood gas pH level of the patient. The ventilation setting control of the ventilator comprises (a) a minute ventilation (VE) control to set the VE level setting on the ventilator; (b) a ventilator breathing frequency (f) control to set the (f) level setting on the ventilator; (c) an intermittent mandatory ventilation rate (IMV) control to set the IMV level setting on the ventilator ; (d) a tidal volume (VT) control to set the VT level setting on the ventilator; (e) a breathing gas flow rate (V) control to set the (V) level setting on the ventilator; (f) a pressure limit control to set the pressure limit level setting on the ventilator; (g) a work of breathing (WOB) control to set the WOB level setting on the ventilator ; (h) a pressure support ventilation (PSV) control to set the PSV level setting on the ventilator; (i) a positive end expiratory pressure (PEEP) control to set the (PEEP) level setting on the ventilator ; (j) a continuous positive airway pressure (CPAP) control to set the CPAP level setting on the ventilator; or (k) a fractional inhaled oxygen concentration (FIO2) control to set the FIO2 level setting on

the ventilator .

- ...Preferred Device: The ventilator further comprises (a) an oxygen control subsystem; (b) actuator(s); (c) display (62), where the processing subsystem (40) provides the desired level settings of the ventilator setting controls to the display; and (b) an alarm (21) for notifying an operator of the ventilator that the level settings of the ventilator setting has been adjusted...
- ...Preferred Component: The feedback .system adjusts the level setting(s) of the ventilator setting controls to vary (a) a minute ventilation (VE) level; (b) a ventilator breathing frequency (f) level; (c) a tidal volume (VT) level; (d) a breathing gas flow...
- ...WOB) level; (g) a pressure support ventilation (PSV) level; (h) a positive end expiratory pressure (PEEP) level; (i) a continuous positive airway pressure (CPAP) level; or (j) a fractional inhaled oxygen concentration (FIO2) level, to maintain the sufficiency of...
- ...patient. It generates at least one driver signal responsive to the response signal. The feedback **system** comprises (a) a source of breathing gas(es); (b) a pneumatic subsystem in communication with...
- ...the breathing circuit; and (c) actuator(s) coupled to the pneumatic subsystem and to the ventilator setting control so that the breathing gas supplied to the patient is governed in response to the driver signal. The processing subsystem has neural network(s) and processor. The processor, in determining the desired level settings of the ventilator setting controls, generates ventilation data from the output signals of the sensors. It applies at least a portion of the ventilation data and at least a portion of the ventilator setting parameter signal to the neural network.

... Title Terms: PROCESS;

International Patent Class (Main): A61M-016/00
International Patent Class (Additional): A62B-007/00

(Item 61 from file: 350) 31/3, K/61DIALOG(R) File 350: Derwent WPIX (c) 2004 Thomson Derwent. All rts. reserv. 013684079 **Image available** WPI Acc No: 2001-168303/200117 XRAM Acc No: C01-050170 XRPX Acc No: N01-121405 Ventilation support monitoring system for a ventilator comprises input, sensors, and a processing subsystem that receives the output signals from the sensors and the ventilator setting parameter signal from the input Patent Assignee: UNIV FLORIDA (UYFL); UNIV FLORIDA RES FOUND INC (UYFL) Inventor: BANNER M J; BLANCH P B; EULIANO N R; PRINCIPE J C Number of Countries: 023 Number of Patents: 004 Patent Family: Patent No Date Kind Applicat No Kind Date Week WO 200100264 A1 20010104 WO 2000US18175 A 20000630 200117 AU 200060640 20010131 AU 200060640 Α 20000630 Α 200124 EP 1189649 A1 20020327 EP 2000946958 20000630 Α 200229 WO 2000US18175 Α 20000630 US 6796305 B1 20040928 US 99141735 Ρ 19990630 200464 US 2000608200 Α 20000630 Priority Applications (No Type Date): US 99141735 P 19990630; US 2000608200 A 20000630 Patent Details: Patent No Kind Lan Pg Main IPC Filing Notes WO 200100264 A1 E 54 A61M-016/00 Designated States (National): AU CA JP Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE AU 200060640 A A61M-016/00 Based on patent WO 200100264 EP 1189649 Al E A61M-016/00 Based on patent WO 200100264 Designated States (Regional): AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE US 6796305 A61M-016/00 В1 Provisional application US 99141735 Ventilation support monitoring system for a ventilator comprises input, sensors, and a processing subsystem that receives the output

Abstract (Basic):

from the input

... A ventilation support monitoring system comprises an input that receives at least one ventilator setting parameter signal; sensors for measuring ventilation support parameters; and a processing subsystem connected to receive the output signals from the sensors and the ventilator setting parameter signal from the input.

signals from the sensors and the ventilator setting parameter signal

- A ventilation support monitoring system comprises an input that receives at least one ventilator setting parameter signal; sensors (52) for measuring ventilation support parameters; and a processing subsystem connected to receive the output signals from the sensors and the ventilator setting parameter signal from the input. Each sensor connects to a select one of the...
- ...an output signal based on the measured ventilation support parameter. The processing subsystem has a **processor** and a **memory**. The **processor** runs under **control** of a program stored in the **memory**. It has an intelligence **system** that determines a desired level setting of at least one **ventilator** setting control in response to the

ventilator setting parameter signal and the output signals...

- ...1) a ventilation support monitoring method for a ventilator (20) having selectable ventilator setting controls for governing supply of the breathing gas from the ventilator to the patient, each setting control selectable to a level setting comprising...
- ...a) receiving at least one **ventilator** setting parameter signal indicative of the level setting of one **ventilator** setting control...
- ...c) determining the desired level setting of at least one **ventilator** setting control of the **ventilator**. Each sensor is connected to a select one of the patient or the breathing circuit...
- ...2) a **method** for differential determination of desired level settings of a **ventilator** comprises...
- ...a) supplying a breathing gas from the **ventilator** to a patient via a breathing circuit in fluid communication with the **ventilator** and at least one lung of the patient...
- ...c) receiving **ventilator** setting parameter signals indicative of the level settings of the **ventilator** setting controls...
- ...at least a portion of the ventilation data and at least a portion of the ventilator setting parameter signals...
- ...f) converting the selected portion of the ventilation data and the selected portion of the **ventilator** setting parameter signals into numerical expressions...
- ...i) determining at least one of the desired level settings of the **ventilator** setting controls using the neural network in accordance with the input numerical expressions...
- ... For a **ventilator** supplying breathing gas to a patient via a breathing circuit in fluid communication with at least one lung of a patient for treating patients with **respiratory** failure...
- ...b) if it is beyond the capacity or capability of small or disabled patients. The **ventilator** monitor **system** delivers the most appropriate **mode** and intra- **mode**, the most appropriate quality and quantity of ventilation support required by the patient's current physiological needs by (a) receiving **ventilator** support signals indicative of the sufficiency of ventilation support received by the patient; (b) receiving at least one **ventilator** signal indicative of the level settings of the **ventilator** setting controls of the **ventilator**; and (c) determining the desired level settings of the **ventilator** setting controls of the **ventilator** to provide the appropriate quality and quantity of ventilation support to the patient
- ... The figure shows a block diagram of the ventilator monitor system .
- ... **Ventilator** (20 Technology Focus:
- ... level of the patient; or (i) arterial blood gas pH level of the patient. The **ventilator** setting parameter signal and the desired level setting for the **ventilator** setting control of the **ventilator** comprise (a) a minute ventilation (VE) signal indicative of the VE

level set on the ventilator; (b) a ventilator breathing frequency
(f) signal indicative of the f level set on the ventilator; (c) a tidal volume (VT) signal indicative of the VT level set on the ventilator; (d) a breathing gas flow rate (V) signal indicative of the V level set on the ventilator; (e) a pressure limit signal indicative of the pressure limit set on the ventilator; (f) a work of breathing (WOB) signal indicative of the WOB level set on the ventilator; (q) a pressure support ventilation (PSV) signal indicative of the PSV level set on the ventilator; (h) a positive end expiratory pressure (PEEP) signal indicative of the PEEP level set on the ventilator; (i) a continuous positive airway pressure (CPAP) signal indicative of the CPAP level set on the ventilator; or (j) a fractional inhaled oxygen concentration (FIO2) signal indicative of the FIO2 level set on the ventilator . Preferred System : The system further comprises (a) a display (62), where the processing subsystem (40) provides the desired level settings of the ventilator setting controls to the display; and (b) an alarm (21) for notifying an operator of the ventilator that the level settings of the ventilator setting controls differs from the determined desired level settings of the ventilator setting controls...

- ...processing subsystem has (a) neural network(s) under control of a program stored in the **memory**, and (b) a mechanism for training the neural work. It is programmed with a set...
- ...rules, and identifies ventilation data used to (a) determine the desired level settings of the **ventilator** setting controls; (b) identifies a subset of the ventilation data for display; and (c) provides...
- ...ventilation data to the display. The processing subsystem provides the desired level settings of the **ventilator** controls to the display. The **processor**, in determining the desired level settings of the **ventilator** setting controls, generates ventilation data from the output signals of the sensors. It applies the...
- ...data prior to applying the portion of the ventilation data and the portion of the **ventilator** setting parameter signal to the neural network to generate the desired level settings of the **ventilator** setting controls.

... Title Terms: SYSTEM ;

International Patent Class (Main): A61M-016/00

DIALOG(R) File 350: Derwent WPIX (c) 2004 Thomson Derwent. All rts. reserv. 012104071 **Image available** WPI Acc No: 1998-520983/199844 XRPX Acc No: N98-406879 Graphic user interface for patient ventilator - has on-screen buttons allowing user to select proposed ventilator setting in any order and value, while processor controls ventilator using currently used parameters Patent Assignee: NELLCOR PURITAN BENNETT INC (NELL-N); ARNETT D (ARNE-I); BUTTERBRODT J (BUTT-I); FERGUSON H L (FERG-I); SANBORN W G (SANB-I); WALLACE C L (WALL-I) Inventor: ARNETT D; BUTTERBRODT J; FERGUSON H L; SANBORN W G; WALLACE C L Number of Countries: 022 Number of Patents: 010 Patent Family: Patent No Date Kind Applicat No Kind Date Week WO 9841270 A1 19980924 19980224 WO 98US3756 Α 199844 В AU 9863398 AU 9863398 Α 19981012 Α 19980224 199907 US 97818201 US 5915379 Α 19990629 Α 19970314 199932 EP 98907643 EP 968019 Α1 20000105 Α 19980224 200006 WO 98US3756 Α 19980224 AU 735793 AU 9863398 В 20010712 Α 19980224 200147 JP 98540524 19980224 JP 2001521415 W 20011106 Α 200203 WO 98US3756 Α 19980224 US 97818201 US 6369838 В1 20020409 Α 19970314 200227 US 99314860 19990519 Α US 20020099477 Α1 20020725 US 97818201 19970314 Α 200254 19990519 US 99314860 Α US 200299824 Α 20020315 EP 968019 B1 20030212 EP 98907643 Α 19980224 200313 WO 98US3756 Α 19980224 DE 69811346 F. 20030320 DE 611346 19980224 Α 200327 EP 98907643. Α 19980224 WO 98US3756 Α 19980224 Priority Applications (No Type Date): US 97818201 A 19970314; US 99314860 A 19990519; US 200299824 A 20020315 Patent Details: Patent No Kind Lan Pg Main IPC Filing Notes WO 9841270 A1 E 44 A61M-016/00 Designated States (National): AU CA JP Designated States (Regional): AT BE CH DE DK ES FI FR GB GR IE IT LU MC NL PT SE AU 9863398 Α A61M-016/00 Based on patent WO 9841270 US 5915379 A61M-016/00 Α EP 968019 A1 E A61M-016/00 Based on patent WO 9841270 Designated States (Regional): AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE AU 735793 A61M-016/00 Previous Publ. patent AU 9863398 Based on patent WO 9841270 JP 2001521415 W 81 A61M-016/00 Based on patent WO 9841270 US 6369838 В1 A61M-016/00 Cont of application US 97818201 US 20020099477 A1 G05D-023/00 Cont of application US 97818201 Cont of application US 99314860 Cont of patent US 5915379 Cont of patent US 6369838 EP 968019 B1 E A61M-016/00 Based on patent WO 9841270

Designated States (Regional): AT BE CH DE DK ES FI FR GB GR IE IT LI LU

31/3, K/76

MC NL PT SE

(Item 76 from file: 350)

DE 69811346 E A61M-016/00 Based on patent EP 968019 Based on patent WO 9841270

Graphic user interface for patient ventilator - ...

- ...has on-screen buttons allowing user to select proposed ventilator setting in any order and value, while processor controls ventilator using currently used parameters
- ...Abstract (Basic): The interface comprises programmable processor (30) responsive to selected ventilation parameters for controlling respirator to ventilate patient, and a memory (35) connected to the processor for storing ventilation parameters. The interface also includes user inputs (25) and a display (50) for displaying ventilation parameters, including those used by the processor to control the respirator and proposed ventilation parameters. The user inputs cooperate with the memory and the display for selecting one of the proposed ventilation parameters and for assigning values...
- ...The proposed ventilator parameters may be selected in any order and values assigned to the proposed parameters while the processor controls ventilator using currently used values of the ventilation parameters. A user accepts one or mo re assigned values of the proposed ventilator parameters by pressing a button and the processor stores the assigned proposed ventilator values in the memory, and controls the ventilator using the newly stored values. Preferably, the display further includes a graphical representation of a...

... Title Terms: PROCESSOR;

International Patent Class (Main): A61M-016/00 ...
International Patent Class (Additional): A61B-005/08

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31/3,K/93
              (Item 93 from file: 350)
DIALOG(R) File 350: Derwent WPIX
(c) 2004 Thomson Derwent. All rts. reserv.
009748249
             **Image available**
WPI Acc No: 1994-028100/199404
XRPX Acc No: N94-021801
                 equipment including nebuliser for atomised spray - has
   Respiratory
  computerised monitoring system recording applied doses of gas on
  magnetic tape or memory chip
Patent Assignee: TAEMA (TAEM-N); AIR LIQUIDE SANTE INT (AIRL )
Inventor: DESFORGES D; WILLEMOT J
Number of Countries: 015 Number of Patents: 009
Patent Family:
Patent No
              Kind
                     Date
                             Applicat No
                                             Kind
                                                    Date
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EP 580517
                  19940126 ⋅EP 93401912
                                                  19930723
               Α1
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FR 2693910
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                                             Α
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EP 580517
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               В1
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                                              Α
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DE 69330041
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               Ε
                             DE 630041
                                                  19930723
                                              Α
                                                            200130
                             EP 93401912
                                                  19930723
                                              Α
ES 2156123
               Т3
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                             EP 93401912
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                                                  19930723
                                                            200141
Priority Applications (No Type Date): FR 929075 A 19920723
Patent Details:
Patent No Kind Lan Pg
                         Main IPC
                                      Filing Notes
EP 580517
                     5 A61M-016/10
              A1 F
   Designated States (Regional): BE DE DK ES GR IT LU NL PT SE
FR 2693910
              Α1
                    10 A61M-016/10
BR 9302959
              Α
                       A61M-016/00
CA 2101044
              A F
                       A61M-011/00
ZA 9305317
                    12 A61M-000/00
              Α
US 5560353
              Α
                     5 A61M-016/00
                                     Cont of application US 9395709
              B1 F
EP 580517
                       A61M-016/10
   Designated States (Regional): BE DE DK ES GR IT LU NL PT SE
DE 69330041
              Ε
                       A61M-016/10
                                     Based on patent EP 580517
ES 2156123
              Т3
                       A61M-016/10
                                      Based on patent EP 580517
   Respiratory
                 equipment including nebuliser for atomised spray...
```

- ...has computerised monitoring system recording applied doses of gas on magnetic tape or memory chip
- ... Abstract (Basic): The respiratory equipment includes a nebuliser (1) in a circuit (2) between a source of gas (3) and the patient's respiratory channels. A three channel valve (5) is fitted in the dose of carrier gas, and ...
- ...recorded, either on a multi-track magnetic tape or on a non-volatile or `flash' memory chip. This information includes the number and duration of the pulses applied when operating in one of several modes
- ... Abstract (Equivalent): A system for supplying to a respiratory tract of a user a plurality of discrete puffs of at least one gas, each of the puffs containing particles of at least one active product; the system comprising ...

...a transportable **memory** storage unit for transporting the puff sequence program...

...means for the sequence-control programmable means to accept the puff sequence program from the **memory** storage unit and for recording timing parameters of the sequence of the puffs on the **memory** storage unit; and a programing station for entering the puff sequence program onto the **memory** storage unit...

...Title Terms: COMPUTER; International Patent Class (Main): A61M-000/00 ...

... A61M-011/00 ...

... A61M-016/00 ...

... A61M-016/10

31/3,K/100 (Item 100 from file: 350) DIALOG(R) File 350: Derwent WPIX (c) 2004 Thomson Derwent. All rts. reserv. 009014807 **Image available** WPI Acc No: 1992-142143/199218 XRPX Acc No: N92-106338 Mobile respirator monitor with pressure gauge - has transmitter with control for spacing of transmission signals, and identification signal generator Patent Assignee: UWATEC AG (UWAT-N); HOISL I (HOIS-I) Inventor: MOCK M; VOLLM E; VOELLM E; MUECK M; VOELLM E B Number of Countries: 016 Number of Patents: 010 Patent Family: Patent No Kind Date Applicat No Kind Date Week DE 4033292 19920423 DE 4033292 Α Α 19901019 199218 В WO 9206889 19920430 A1 WO 91EP1982 Α 19911018 199220 EP 550649 19930714 A1 EP 91918293 Α 19911018 199328 WO 91EP1982 Α 19911018 EP 550649 19940504 **B1** EP 91918293 Α 19911018 199418 WO 91EP1982 Α 19911018 DE 59101589 G 19940609 DE 501589 Α 19911018 199424 EP 91918293 Α 19911018 WO 91EP1982 Α 19911018 JP 6504245 19940519 JP 91516867 Α 19911018 199424 WO 91EP1982 Α 19911018 ES 2056662 19941001 EP 91918293 T3Α 19911018 199440 US 5392771 19911018 Α 19950228 WO 91EP1982 Α 199514 19920817 US 92861832 Α US 5738092 Α 19980414 US 92861832 Α 19920817 199822 US 94311150 Α 19940923 US 96720215 Α 19960926 EP 550649 B2 20000301 EP 91918293 Α 19911018 200016 WO 91EP1982 Α 19911018 Priority Applications (No Type Date): DE 4033292 A 19901019 Patent Details: Patent No Kind Lan Pg Main IPC Filing Notes DE 4033292 Α 19 EP 550649 B2 G B63C-011/32 Based on patent WO 9206889 Designated States (Regional): AT CH DE ES FR GB IT LI WO 9206889 A1 G 53 B63C-011/32 Designated States (National): JP US Designated States (Regional): AT BE CH DE DK ES FR GB GR IT LU NL SE A1 G EP 550649 B63C-011/32 Based on patent WO 9206889 Designated States (Regional): AT CH DE ES FR GB IT LI EP 550649 B1 G 28 B63C-011/32 Based on patent WO 9206889 Designated States (Regional): AT CH DE ES FR GB IT LI DE 59101589 G B63C-011/32 Based on patent EP 550649 Based on patent WO 9206889 JP 6504245 B63C-011/32 W Based on patent WO 9206889 ES 2056662 Т3 B63C-011/32 Based on patent EP 550649 US 5392771 Α 18 A62B-007/00 Based on patent WO 9206889 US 5738092 Α 18 A62B-007/00 Div ex application US 92861832 Cont of application US 94311150 Div ex patent US 5392771

Mobile respirator monitor with pressure gauge...

... Abstract (Basic): The mobile **respirator** monitor contains a pressure sensor for the **respirator** pressure containers, a transmitter of

- signals corresp. to the pressure measuring at intervals, a receiver...
- ...interval and compared in the receiver with a stored identification signal. Received signals are only **processed** on the signal coincidence
- ...Abstract (Equivalent): The mobile respirator monitor contains a pressure sensor for the respirator pressure containers, a transmitter of signals corresp. to the pressure measuring at intervals, a receiver ...
- ...interval and compared in the receiver with a stored identification signal. Received signals are only **processed** on the signal coincidence ...
- ...EP-550649 A monitoring device for a portable breathing apparatus having: a pressure measuring means, which detects the pressure in one or more pressure containers of the breathing apparatus by means of a pressure sensor and emits an electrical pressure signal, which is representative...
- ...to this receiving means, which receives the transmission signal, emitted by the transmission means; a microprocessor means, arranged in the receiver means, which is controlled by a program, stored in a memory arranged in this receiving means, said microprocessor means calculating the pressure value, measured by the pressure measuring means from the received transmission...
- ...which is assigned to that of an associated individual transmitter means is stored in the **memory** of the receiver means, that the receiver means comprises a comparison means, which uses this...
- ... Abstract (Equivalent): The **respirator** monitor **device** has a manometer for sensing the pressure in the pressure container of the **breathing apparatus** and has a transmitter so that a signal corresponding to the pressure is transmitted at...
- ...received and tested by a receiver. If the identification signal matches an identification comparison signal **stored** in the receiving **device**, the measured pressure value is displayed on a display device...

 International Patent Class (Main): A62B-007/00 ...

 International Patent Class (Additional): A62B-007/04 ...

... A62B-009/00 ...

... A62B-027/00

31/3,K/104 (Item 104 from file: 350)

DIALOG(R) File 350: Derwent WPIX

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007472113

WPI Acc No: 1988-106047/198816

XRPX Acc No: N88-080439

processor - controlled monitoring of respiration - storing component models of appts. and patient and recalling to form complete model

Patent Assignee: INGENIEUR DRESDEN (INGE-N)

Inventor: BOEHME B; KAISER S; MORGENSTE U; WOSCHECH S

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No Kind Date Applicat No Kind Date Week.

DD 251706 A 19871125 DD 293085 A 19860730 198816 B

Priority Applications (No Type Date): DD 293085 A 19860730

processor - controlled monitoring of respiration...

- ...storing component models of appts. and patient and recalling to form complete model
- ...Abstract (Basic): are formed from the appts. parameters and the parameters of its elements. A patient component model is defined from identification characteristics. Both component models are stored in the computer section of the artificial respiration system. These are then called up from the memory and combined to form a complete model
- ...If there are any changes of parameters during respiration the necessary **ventilator** setting may be determined, without harm to the patient, by simulation...
- ... USE/ADVANTAGE Enables doctor to respond by **ventilator** adjustment to changes of parameters of appts. or of the patient, without causing any additional

Title Terms: PROCESSOR ;

International Patent Class (Additional): A61M-016/00

31/3,K/105 (Item 105 from file: 350)

DIALOG(R) File 350: Derwent WPIX

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007254956

WPI Acc No: 1987-251963/198736

XRPX Acc No: N87-188535

Programmable fluid flow controller for respiratory system - uses transducers to sense parameters for input to control unit which opens or closes distribution circuits

Patent Assignee: SOC FAB INSTR MESUR (INST-N)

Inventor: SILBER G; VINCENT D

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No Kind Date Applicat No Kind Date Week FR 2593299 A 19870724 FR 86696 A 19860120 198736 B

Priority Applications (No Type Date): FR 86696 A 19860120

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

FR 2593299 A 28

Programmable fluid flow controller for respiratory system -

...Abstract (Basic): A number of fluid flow distribution circuits (2) connected to respirators are supplied through a tube (PA) to a pressurised source of air and gas. An electronic control unit (3) contains A/D and D/A converters connected to a microprocessor and its memory and controls the opening or closing of each distribution circuit. The control actions follow a...

... Title Terms: SYSTEM;

International Patent Class (Additional): A61M-016/06 ...

... A62B-007/14

31/3,K/107 (Item 107 from file: 350)

DIALOG(R) File 350: Derwent WPIX

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007042512

WPI Acc No: 1987-042509/198706

XRPX Acc No: N87-032359

Pulmonary ventilator controller for anaesthetised patient - has microprocessor receiving from operator target values for minute volume breathing rate and expiration-inspiration time ratio

Patent Assignee: RUSZ T (RUSZ-I)

Inventor: RUSZ T

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No Kind Date Applicat No Kind Date Week
US 4637385 A 19870120 US 86818005 A 19860113 198706 B

Priority Applications (No Type Date): US 86818005 A 19860113

Patent Details:

Patent No Kind Lan Pg Main IPC Filing Notes

US 4637385 A 6

Pulmonary ventilator controller for anaesthetised patient...

- ...has microprocessor receiving from operator target values for minute volume breathing rate and expiration-inspiration time ratio
- ...Abstract (Basic): The pulmonary ventilator system has a bellows assembly and a source of driving gas connected by a series branch...
- ...controlled switching valve and a motor-controlled flow-rate-controlling valve. A controller including a **microprocessor** senses the position of the flow-rate-controlling valve via a mechanical to electrical transducer...
- ...has outputs connected to and controlling the switching valve and the motor. Programmed in the memory are the maximum flow rate capacity of the flow-rate-controlling valve and the maximum capacity of the bellows. The microprocessor is capable of receiving from an operator his target values for minute volume, breathing rate...
- ...the flow-controlling valve and or greater than the bellows can handle, it reinstructs the **ventilator system** to employ a new and realizable value of breathing rate and/or expiration time to...

... Title Terms: MICROPROCESSOR;

International Patent Class (Additional): A61M-016/00

31/3,K/113 (Item 113 from file: 350) DIALOG(R) File 350: Derwent WPIX (c) 2004 Thomson Derwent. All rts. reserv. 003277595 WPI Acc No: 1982-C5580E/198210 Patient respiration monitoring appts. - uses transducer sensing of air-way pressure and volume flow for input to computerised processing and monitoring circuit Patent Assignee: TOKYO SHIBAURA ELECTRIC CO (TOKE) Inventor: ITOH A Number of Countries: 005 Number of Patents: 004 Patent Family: Patent No Kind Kind Date Applicat No Date Week 19820303 EP 81106455 EP 46570 Α Α 19810819 198210 B Α US 4444201 19840424 US 81294290 Α 19810819 198419 EP 46570 В 19850717 198529 DE 3171395 G 19850822 198535 Priority Applications (No Type Date): JP 80118162 A 19800827 Patent Details: Patent No Kind Lan Pg Main IPC Filing Notes EP 46570 A E 25 Designated States (Regional): DE FR GB NL EP 46570 B E Designated States (Regional): DE FR GB NL ... Abstract (Basic): One end of the transducer (14) is connected to a tube (12) intubated into the respiratory tract of the patient, whilst the other end is connected to an artificial respiration device (18) through a bellows type tube (16). The transducer enables measurement to be taken of the amount of air breathed by the patient and the airway pressure in his respiratory tract. A pressure in the transducer is conducted to the manometer (22) which is in... ... via an analog-to- digital converter (30) in the processing circuit which also includes a $extstyle{CPU}$, and bubble $extstyle{memory}$ in addition to video $extstyle{RAM}$, ROM and RAM memories. The device has an additional keyboard (46) for data entry and output monitoring (44... ... Title Terms: COMPUTER ; International Patent Class (Additional): A61B-005/08 ...

... A61M-016/00

31/3,K/114 (Item 114 from file: 350) DIALOG(R) File 350: Derwent WPIX (c) 2004 Thomson Derwent. All rts. reserv. 003120224 WPI Acc No: 1981-N0277D/198151 Patients respiratory parameter determn. appts. - uses time controlled integrator connected to flow sensor and periodically cleared and calculator to obtain pneumatic parameters Patent Assignee: DRAEGERWERK AG (DRAG Inventor: BAEUERLE R; HORNAUER D Number of Countries: 005 Number of Patents: 007 Patent Family: Patent No Applicat No Kind Date Kind Date GB 2077444 Α 19811216 GB 8117329 Α 19810605 198151 DE 3021326 Α 19811217 198152 FR 2483769 Α 19811211 198203 SE 8102322 Α 19820104 198203 NL 8101088 Α 19820104 198205 GB 2077444 В 19840222 198408 SE 453884 В 19880314 198813 Priority Applications (No Type Date): DE 3021326 A 19800606 Patent Details: Patent No Kind Lan Pg Main IPC Filing Notes GB 2077444 Patients respiratory parameter determn. appts... ...uses time controlled integrator connected to flow sensor and periodically cleared memory and calculator to obtain pneumatic

parameters

... Abstract (Basic): connected to a calculating unit (6), and optionally to a storage unit (8). During each respiratory cycle the monitoring unit (7) supplies the calculating unit (6) with at least two sets...

...the volume from which the calculating unit (6) then calculates the required parameters of the respiratory system...

...pressure. Pref. the calculations are performed using a Least squares technique. The stored values are cleared at the end of each operating cycle...

... Title Terms: MEMORY ;

International Patent Class (Additional): A61B-005/08 ...

... A61M-016/00

31/3,K/117 (Item 117 from file: 350)

DIALOG(R) File 350: Derwent WPIX

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003021296

WPI Acc No: 1981-C1309D/198110

Pulmonary analyser to compute respiratory characteristics - having spirometer for exhaled breath, VCO, digital computer , RAM , ROM and

nine-digit display

Patent Assignee: JONES MED INSTRU (JONE-N)

Inventor: HARWOOD C; JONES W C

Number of Countries: 001 Number of Patents: 001

Patent Family:

Patent No Kind Date Applicat No Kind Date Week US 4250890 A 19810217 198110 B

Priority Applications (No Type Date): US 7914423 A 19790223

Pulmonary analyser to compute respiratory characteristics...

- ...having spirometer for exhaled breath, VCO, digital computer, RAM ROM and nine-digit display
- ... Abstract (Basic): The self-contained, portable system is for measuring and computing respiratory parameters of a test subject undergoing forced expired breathing manoeuvres according to instructions including
- ...receiving the exhaled breath of the subject for generating a measurement signal, a miniaturised digital **computer** for receiving the measurement signal and a visual display for presenting alpha-numeric characters under control of the **computer** to generate indicia representative of the computed parameter results...
- ...The computer further includes a central processing unit and a voltage control oscillator interconnected between the central processing unit and the spirometer for receiving the measurement signal from the spirometer and converting the same to digital signals for averaging by the central processing unit to eliminate random noise.

... Title Terms: COMPUTER;

International Patent Class (Additional): A61B-005/08

31/3,K/126 (Item 126 from file: 347)

DIALOG(R) File 347: JAPIO

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06590221 **Image available**

VENTILATION DATA PROCESSING METHOD AND DEVICE

PUB. NO.: 2000-176016 [JP 2000176016 A]

PUBLISHED: June 27, 2000 (20000627)

INVENTOR(s): UTSUNOMIYA HIDETAKA

YOKOO TADASHI

APPLICANT(s): NIPPON KODEN CORP

APPL. NO.: 10-354750 [JP 98354750] FILED: December 14, 1998 (19981214)

VENTILATION DATA PROCESSING METHOD AND DEVICE

INTL CLASS: A61M-016/00

ABSTRACT

...the mouth of a patient, and the outputs of these sensors are inputted to a ventilation data processing device. After starting the operation of the ventilation data processing device, the outputs of both the sensors are read to recognize one respiration from expiration flow data. In the one recognized respiration, expiration end and positive expiration end pressure-(PEEP) are determined, and the respective values are stored in a memory 8. After PEEP is changed, it is judged whether the respiration is performed n2 times or more, and in the case of YES, the respective changes are determined from the expiration end and PEEP in the memory 8. The compliance is calculated by use of both the changes, and the result is stored in the memory 8 and also displayed on a display means 9.

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```
Set
        Items
                Description
                (VENTILAT? OR RESPIRAT? OR BREATH?) (3N) (DEVICE? OR UTENSIL?
S1
         9643
              OR APPARAT? OR TOOL? OR IMPLEMENT? OR INSTRUMENT? OR APPLIAN-
             C? OR EQUIPMENT? OR MACHINE? OR MECHANIC?)
S2
                VENTILATOR? OR VENTILATER? OR RESPIRATOR? OR RESPIRATER? OR
              HFV OR IMV OR IPAP OR CPAV OR PEEP OR CPAP
                CLEAR? OR CANCEL? OR ERASE? OR ERASUR? OR ERASING? OR DELE-
S3
      1022466
             T? OR OVERRID? OR OVERWRIT? OR OVER() (RIDE? OR RIDING OR WRIT-
             ?) OR REPROGRAM? OR REMOV?
S4
      1279284
                OPERAT? OR FUNCTION?
S5
       560068
                PERFORMANC? OR WORKING? OR EXECUTI?
       674783. DATA? OR PROGRAM?
S6
S7
       372635
                RUN OR RUNS OR RUNNING OR RAN
S8 .
       104684
                (READ? OR SCAN? OR DECOD?) (5N) (WRIT? OR CODE? OR CODING? OR
              CODIF?)
S9
        16743
                (CHIP? OR SMART? OR DEBIT? OR PROGRAMABL? OR PROGRAMMABL?) -
             (3N) CARD? OR SMARTCARD? OR CHIPCARD?
       145797
S10
                (STORE? OR STORING? OR STORAGE) (3N) (DEVICE? OR MEDIUM? OR -
             ELECTRONIC? OR OPTIC? OR MAGNET?) OR USER?()INTERFACE?
S11
       318129
                CACHE? OR MEMORY? OR RAM OR (EXTERNAL OR REMOVABL? OR DETA-
             CHABL? OR STANDALONE OR STAND()ALONE OR PORTABL OR INSERTABL?-
             )(2N)(UNIT? OR DEVICE?)
S12
       246300
                CPU OR CPUS OR PROGRAM? () CONTROL? OR PROCESS? (2N) CONTROL? -
             OR MICROPROCESS? OR DATAPROCESS? OR CENTRALPROCESS? OR (MICRO
             OR DATA OR CENTRAL) () PROCESS?
S13
       143057 PROCESS?()UNIT? OR WORKSTATION? OR WORK()STATION? OR DESKT-
             OP? OR DESK() (TOP OR TOPS) OR SERVER?
       363805
S14 ·
                COMPUTER OR COMPUTERS OR PC OR PCS
S15
      1376491
                METHOD? ?
               SYSTEM? ?
S16
      1199862
S17
      1064521
                PROCESS??
S18
       470421
                PROCEDUR?
       605450
S19
                TECHNIQU?
       645646
S20
                MODE? ?
       103710
S21
                IC=(A62B? OR A61M? OR F16K? OR A61B?)
S22
         6584
                S1:S2 AND S21
      49516
              S22 OR S1:S2
S23
S24
                S23 AND S9:S11
        12315
S25
               S23 AND S12:S14
        17190
S26
         7193
                S24 AND S25
S27
                S26 AND S3(5N)S4:S11
         1990
S28
                S27 AND S1:S2(5N)S9:S14
         102
S29
                S27 AND S15:S20(5N)S3
         1202
S30
                S29 AND S21
          136
S31
          211
                S28 OR S30
S32
          211
                IDPAT (sorted in duplicate/non-duplicate order)
? show files
File 348: EUROPEAN PATENTS 1978-2004/Oct W01
         (c) 2004 European Patent Office
File 349:PCT FULLTEXT 1979-2002/UB=20041007,UT=20040930
         (c) 2004 WIPO/Univentio
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32/3, K/2
             (Item 2 from file: 348)
DIALOG(R) File 348: EUROPEAN PATENTS
(c) 2004 European Patent Office. All rts. reserv.
00744748
SYSTEM FOR OPTIMIZING CONTINUOUS POSITIVE AIRWAY PRESSURE FOR TREATMENT OF
    OBSTRUCTIVE SLEEP APNEA
SYSTEM FUR DIE OPTIMIERUNG DES KONTINUIERLICHEN, POSITIVEN ATEMWEGDRUCKS
    ZUR BEHANDLUNG DES ATEMSTILLSTANDES IM SCHLAF BEI VERLEGTEN ATEMWEGEN
SYSTEME PERMETTANT D'OPTIMISER LA PRESSION POSITIVE CONTINUE DES VOIES
    RESPIRATOIRES POUR LE TRAITEMENT DE L'APNEE OBSTRUCTIVE DU SOMMEIL
PATENT ASSIGNEE:
  PURITAN-BENNETT CORPORATION, (1144916), 9728 Pflumm Road, P.O. Box 15915,
    Lenexa, KS 66285-5915, (US), (Proprietor designated states: all)
  NEW YORK UNIVERSITY, (300274), 550 First Avenue, New York, NY 10016, (US)
    , (Proprietor designated states: all)
INVENTOR:
  RAPOPORT, David, M., 214 West 17th Street 4A, New York, NY 10011, (US)
  NORMAN, Robert, G., 306 Shore Drive, New Windsor, NY 12553, (US)
LEGAL REPRESENTATIVE:
  Belcher, Simon James (58311), Urquhart-Dykes & Lord Tower House Merrion
    Way, Leeds LS2 8PA, (GB)
                              EP 759791 A1 970305 (Basic) = (US) 5490502
EP 759791 B1 020814
PATENT (CC, No, Kind, Date):
                              WO 9532016 951130
APPLICATION (CC, No, Date):
                              EP 95920447 950516;
                                                   WO 95US6069 950516
PRIORITY (CC, No, Date): US 246964 940520
DESIGNATED STATES: BE; CH; DE; ES; FR; GB; LI; SE
RELATED DIVISIONAL NUMBER(S) - PN (AN):
  EP 1172123 (EP 2001126195)
INTERNATIONAL PATENT CLASS: A61M-016/00; A61B-005/00; G06F-017/00
NOTE:
  No A-document published by EPO
LANGUAGE (Publication, Procedural, Application): English; English; English
FULLTEXT AVAILABILITY:
Available Text Language
                            Update
                                     Word Count
      CLAIMS B
                (English)
                            200233
                                        543
      CLAIMS B
                           200233
                                        465
                 (German)
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637

8972

10617

10617

INTERNATIONAL PATENT CLASS: A61M-016/00 ...

(French)

(English)

200233

200233

... A61B-005/00

CLAIMS B

Total word count - document A Total word count - document B

Total word count - documents A + B

SPEC B

- ...SPECIFICATION an optimum value in the treatment of obstructive sleep apnea, and more particularly to a **breathing device** which maintains constant positive airway pressure and method of use which analyzes an inspiratory flow...
- ...obstruction of the upper airway occurring during sleep. The obstruction results in a spectrum of **respiratory** disturbances ranging from the total absence of airflow (apnea) to significant obstruction with or without reduced airflow (hypopnea and snoring), despite continued **respiratory** efforts. The morbidity of the syndrome arises from hypoxemia, hypercapnia, bradycardia and sleep disruption associated...

- ...onset of sleep and may be exaggerated in OSAS.

 Since 1981, continuous positive airway pressure (CPAP) applied by a tight fitting nasal mask worn during sleep has evolved as the most...
- ...535-542, discusses various polysomnographic techniques.

 Despite its success, limitations to the use of nasal CPAP exist.

 These mostly take the form of discomfort from the mask and the nasal pressure...
- ...4655213 and US-5065756, as well as in "Therapeutic Options For Obstructive Sleep Apnea", Garay, Respiratory Management, Jul/Aug 1987, pp. 11-15; and "Techniques For Administering Nasal CPAP", Rapaport, Respiratory Management, Jul/Aug 1987, pp. 18-21. Minimizing the necessary pressure remains a goal of...
- ...Bécause of this, most sleep laboratories currently prescribe the setting for home use of nasal CPAP pressure based upon the single highest value of pressures needed to obliterate apneas during a...
- ...in the patient's airway does not occur. In particular, the invention relates to a **breathing device** for adjusting a controlled positive pressure to the airway of a patient by detecting flow...limitation has been detected and on the previous actions taken by the system.

The preferred **breathing device** or **apparatus** consists of a flow generator, such as a variable-speed blower, a flow sensor, an analog to digital converter, a **microprocessor**, and a pressure controller, such as a blower motor speed control circuit, a patient connection...

- ...air through the flow sensor to the patient via a hose and nasal coupling. The microprocessor obtains the flow waveform from the digitized output of the flow sensor. Using the method of the present invention described herein, the microprocessor adjusts the speed of the blower via the motor control circuit to change the air...
- ...may be provided to measure the actual pressure in the patient hose. In addition, the **microprocessor** may store measured pressure and flow waveform values in its data **memory** to provide a history for real-time or off-line processing and analysis.

 Other features...
- ...waveform of the airflow of a 30 second epoch to a sleeping patient from a CPAP generator, with a CPAP pressure of 10 cm H2))O.
 - FIG. 2 is the waveform of the airflow of a 30 second epoch to the sleeping patient of FIG. 1, from a CPAP generator, with a CPAP pressure of 8 cm H2))O.
 - FIG. 3 is the waveform of the airflow of a 30 second epoch to the sleeping patient of FIG. 1, from a CPAP generator, with a CPAP pressure of 6 cm H2))O.
 - FIG. 4 is the waveform of the airflow of a 30 second epoch to the sleeping patient of FIG. 1, from a CPAP generator, with a CPAP pressure of 4 cm H2))O.
 - FIG. 5 is the waveform of the airflow of a 30 second epoch to the sleeping patient of FIG. 1, from a CPAP generator, with a CPAP pressure of 2 cm H2))O.
 - FIG. 6 is a simplified cross sectional view of...
- ...with the invention.
 - FIG. 10 is a flow diagram illustrating one technique for adjusting the CPAP pressure, in accordance with the invention.
 - FIG. 11 is a transition diagram of a three...

- ...plot of a total flow signal and a derivative of an inspiratory waveform depicting a **respiratory** effort index.
 - FIG. 16 contains a table of the probability factors used to modify the \dots DETAILED DISCLOSURE OF THE INVENTION
 - FIGS. 1-5 illustrate the waveforms of flow from a CPAP generator, obtained during the testing of a patient, in sleep studies. In these tests, the patient was wearing a CPAP mask connected to an air source, in the manner illustrated in US-5 065 756...
- ...the source of air.
 - FIG. 1 illustrates a "normal" waveform, in this instance with a **CPAP** pressure of 10 cm H2))O. This pressure was identified as corresponding to apnea free...
- ...airway occurs, prior to the occurrence of frank apnea, periodic breathing or arousal.
 - When the CPAP pressure was decreased to 8 cm H2))O, as illustrated in FIG. 2, a partial...
- ...FIG. 4, when the controlled positive pressure was reduced to 4 cm. Reductions in the CPAP pressure from the pressure of apnea free respiration resulted in snoring by the patient. When...
- ...to the collapsible tube 12. With reference to FIG. 7, in this experiment, a commercial CPAP flow generator 14 is coupled to the "distal" end of the Starling resistor 10, and...
- ...the column 13 set between 5 and 15 cm H2))O. The airflow from the CPAP flow generator was started at a pressure of 14 cm H2))O, then sequentially decreased...
- ...e., at the port of the sinusoidal generator 15, and the lower curve illustrates the CPAP pressure. The gradations at the top of FIG. 8 denote seconds. FIG. 8 thus reflects...
- ...FIGS. 1-5, are employed in order to control the flow of air from a CPAP generator, to thereby minimize the flow of air from the generator while still ensuring that...
- ...does not occur.
 - In one embodiment of the invention, as illustrated in FIG. 9, a CPAP mask 20 is connected via tube 21 to receive air from a CPAP flow generator 22. These elements may be of the type disclosed in US-5 065 756, although the invention is not limited thereto, and any conventional CPAP system may alternatively be employed. A conventional flow sensor 23 is coupled to the tube...
- ...is of course apparent that, depending upon the type of flow generator 22, the signal **processor** may directly **control** the flow generator, instead of controlling a flow control device 25.

One method for adjusting the CPAP pressure in accordance with the invention is illustrated in FIG. 10. After the CPAP mask has been fitted to a patient and the CPAP generator has been connected to the mask (step 40), the CPAP pressure is set at a starting pressure. This pressure is a pressure at which flow...

..42).

If it is determined that flow limitation has occurred (step 43) and that the ${\tt CPAP}$ pressure is less than the maximum allowed (step 44), then the ${\tt CPAP}$ pressure is increased by 0.5 cm H2))...at the pressure comparing step 44 the pressure was not less than the maximum allowed

CPAP pressure, then the method returns to the settling step 41 without increasing the CPAP pressure.

If it was determined that a flow limitation was not present (step 43), then...

- ...made (step 46) whether a predetermined time has elapsed following the last change in the CPAP pressure. The predetermined time may be, for example, two minutes. If the predetermined time has...
- ...period step 41. If the predetermined minimum time has elapsed, it is determined whether the CPAP pressure is greater than theminimum allowed pressure (step 47). If it is greater than the minimum allowed pressure, then the CPAP pressure is decreased by 0.5 cm H2))O (step 48), and the method returns...
- ...the settling step 41. Otherwise, the returns to the settling step 41 without decreasing the ${\ CPAP\ }$ pressure.

While the above described example of the method of the invention employed ${\tt CPAP}$ pressure change steps of 0.5 cm H2))O, it is apparent that the invention...

- ...pressure, or "start value," must be available for use when power-on occurs in the **breathing device**. Similarly, the method requires a "therapeutic level" of controlled positive pressure to return to whenever ...
- ...of a valid breath. A valid breath is determined by a cyclical fluctuation in the **respiratory** signal superimposed on the constant system leak. This detection is implemented using a three phase...
- ...art, the logic for the state machine may be programmed into the software of a microprocessor or similar computer hardware.

The total flow signal present within the positive pressure flow generator is used as...to differentiate between the onset of inspiration and mere changes in flow leakage in the $\mbox{breathing}$ \mbox{device} .

The average leak value (ALV) is a calculated running average of the actual flow signal...

- ...Also, the method steps may be applied to the estimated flow signal output of a CPAP generator (which has the constant leak value subtracted out) and the ALV set equal to...
- ...present is based on four shape detection parameters, the sinusoidal index, the flatness index, the **respiratory** effort index and the relative flow magnitude index. The sinusoidal parameter or index is calculated...
- ...parameter or index which ranges from 1 (sinusoidal) to 0 (flat).

 The system calculates the **respiratory** effort index as the ratio of peak derivative (rate of change of flow with respect...
- ...derivative of the inspiratory flow. The ratio of the peak values (B/A) is the "respiratory effort index." This parameter is useful to detect flow limitation in a patient, because an increased respiratory effort is manifested in an increased slope of the inspiratory flow waveform.

The system calculates...allowing calculation of a posterior probability.

The four shape detection parameters (sinusoidal index, flatness index, respiratory effort index and relative flow magnitude index) are used in a mathematical function to determine...

...the patient. The steps of the method may be programmed in the software of a microprocessor or similar computer. As part of the decision process, the system calculates a time weighted majority function (MF... low limit or above the high limit reference values.

FIG 18. shows an alternative therapeutic apparatus. The breathing device 70 is composed of a flow sensor circuit 72 which senses the flow rate of...

...output value which is proportional to the analog voltage output from the flow sensor.

A microprocessor 80 with associated memory 81 and other peripheral circuits executes computer programs which implement the optimizing methods heretofore described. The microprocessor or similar computing device uses the digital output values from a multiplexer 76 and an analog-to-digital converter 78. The microprocessor produces a speed control signal which adjusts a motor speed control circuit 82 which controls...

...72. The speed of the blower determines the pressure in the patient circuit. Thus, the **microprocessor** is able to adjust the pressure of the patient circuit 70 in response to the data values from the flow sensor.

The breathing device 70 may also incorporate a pressure sensor circuit 90 to allow the microprocessor 80 to obtain a direct measurement of the pressure in the patient tubing 74 via the analog to digital converter circuit 78. Such a configuration would allow the microprocessor to maintain the pressure within the maximum and minimum pressure limits established by the prescribing physician. The actual operating pressure levels can be stored in the memory 81 of the microprocessor every few minutes, thus providing a history of pressure levels during the hours of use when the stored data values are read and further processed by a separate computer program.

A signal representative of the speed of the blower could be stored in **memory** instead of the pressure data values; however, such speed values do not change as rapidly...

- ...the home. Detection and measurement of inspiratory and expiratory flow can be from a standard CPAP system with a flow signal output or by a diagnostic system 100 as shown in...
- ...Data values representative of the measured inspiratory and expiratory flow can be logged by a microprocessor 110 in various forms of computer memory 114.

As shown in FIGS. 20 and 21, the detection and measurement of breathing gas...values may be continuously measured and recorded on a data logging device such as a microprocessor 110 having program memory 111 and a storage medium 114. Thus, the recorded flow signal may be analyzed during or after collection to categorize...

- ...airway resistance (not resulting in frank apnea) or to adjust a single prescription pressure of CPAP in a well standardized manner either in the laboratory or on the basis of home...
- ...FIG. 18, the flow waveforms may be recorded in a recording device, such as a microprocessor 80 with associated memory 81. As heretofore described, data values may be recorded while the patient is using a...
- ...is connected to a pressure or flow sensor 104 which supplies data values to a microprocessor 100 via a multiplexer 166 and analog-to-digital converter 118. Software for storing and analyzing the data may be stored in read-only program memory 111, while the data values are stored in random-access memory or non-volatile memory 114. Additionally, an

oximeter 120 and/or similar diagnostic devices may be connected to the patient and multiplexer for generating additional data values for use and storage by the ${\tt microprocessor}$.

An alternative nasal connection could be achieved by using a "standard" nasal cannula commonly used...

...representative of the actual flow waveform shape.

The recording device may be configured with a microprocessor 110 which uses a sample-and-hold circuit, and an analog-to-digital converter 118...

...waveforms. The digitized samples are then stored in time-sequential order in a non-volatile **memory** device 114, e.g. magnetic disk drive, "flash" **memory**, or battery-backed random-access **memory**.

In order to record more than one signal, e.g. flow and pressure waveforms and...patient is using the diagnostic device at home, the digitized waveforms are stored in nonvolatile memory such as flash memory, floppy or hard disk, or battery-powered random-access memory (RAM). One or two additional measurements may optionally be recorded: patient sleeping position from a position...

...value per second for each additional measurement versus fifty values per second for flow), the **memory** storage requirements would not be increased significantly.

After using the diagnostic device to record the desired parameters while sleeping for one or more nights, the patient returns the **device** or data **storage** unit, e.g., a disk or non-volatile **memory** card, to the physician. The physician extracts the data from the storage, and analyzes it...

...and after the required number of nights of data collection, the patient returns the diagnostic **device** with the **stored** data. If the study will be extended, then the patient **removes** the **data** storage module and returns only the module to the physician.

The stored data are analyzed...with the therapy device for the required number of nights. During each night, the therapy device collects and stores the data as described above.

At step 164, the patient returns the therapy **device** or its data **storage** module for analysis of the stored data after the required number of nights of data...

- ...referred to a sleep lab for a more comprehensive study, step 160.

 If the therapy **device** restores normal **breat**hing patterns for the patient, the pressure data are reviewed at step 172 for the proper...
- ...g., eight centimeters of water pressure or less, then the patient would be prescribed conventional CPAP (non-self-adjusting) therapy, step 176.

While several particular forms of the invention have been...

...CLAIMS B1

- A breathing device for optimizing the positive airway pressure to a patient, comprising: means (86) for applying an...
- ...curvature) and an ideal half sinusoidal signal around the same regression eine (curvature standard),
 - * a respiratory effort index (the ratio of peak derivative (rate of change of flow with respect to...

- ...or more of the said indices indicates a flow limitation in the patient.
 - 2. A breathing device as claimed in claim 1, which includes means for decreasing the positive airway pressure whenever the said indices do not indicate a flow limitation in the patient.
 - 3. A **breathing device** as claimed in claim 1, in which the means for using the stored data values...
- ...calculate a sinusoidal index compares the stored data values with a sinusoidal contour.
 - 4. A **breathing device** as claimed in claim 3, in which the means for using the stored data values...
- ...a sinusoidal index correlates the stored data values with a pure sine wave.
 - 5. A **breathing device** as claimed in claim 1, in which the processing means includes means for calculating a...
- ...index includes a weighted coefficient having a range including a value of zero.
 - 6. A **breathing device** as claimed in claim 1, in which the means for determining a flow limitation includes a **microprocessor**.
 - 7. A breathing device as claimed in claim 1, in which the means for storing data values includes random access memory associated with the microprocessor.
 - 8. A **breathing device** as claimed in claim 1, in which the means for applying an initial level of...
- ...the means for increasing the positive airway pressure includes a motor speed controller.
 - 9. A **breathing device** as claimed in claim 1, in which the means for applying an initial level of...

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(Item 5 from file: 348)
DIALOG(R) File 348: EUROPEAN PATENTS
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00506675
INSPIRATORY AIRWAY PRESSURE SYSTEM
DRUCKSYSTEM FUR ATMUNGSWEGE
SYSTEME DE PRESSION INSPIRATOIRE DES VOIES RESPIRATOIRES
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      CLAIMS B
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                                       873
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                                      17128
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... A62B-009/00
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... SPECIFICATION sleep.

32/3, K/5

In order to treat obstructive sleep apnea, the so-called continuous positive airway pressure (CPAP) system has been devised in which a prescribed level of positive airway pressure is continuously...

...the patient's nares and imposes the positive airway pressure on the nasal passages.

The CPAP system meets with objections from patients, however, because the patient must exhale against the positive...

...also a complaint. Also, exhaled carbon dioxide tends to remain in some nasal masks with CPAP therapy.

In prescribing CPAP therapy, it is usually necessary for a patient to spend one or two nights in a sleep treatment laboratory where it is first determined whether the patient has a respiratory disorder such as sleep apnea. If so, the patient is then fitted with a CPAP device whereupon the required gas pressure is determined for providing the necessary air splint to...

...patient-coupled gas delivery device for pressurizing at least a portion of a patient's **respiratory** passages, such as the nasal passages, with a breathable gas, preferably ambient air which may...phase of the breathing cycle, and initiates the pressure increase at that point in the **breathing** cycle. Alternatively, the **apparatus** determines an interval time as the point in the breathing cycle for increasing the inspiratory

...Fig. 10 is a schematic illustration of a pressure transducer circuit; Fig. 11 is a **computer** program flowchart illustrating the START-UP portion of the main routine;

Fig. 12 is a **computer** program flowchart of the MAIN LOOP portion of the main routine;

Fig. 13 is a ${\tt computer}$ program flowchart of the VALVE STEP subroutine;

Fig. 14 is a computer program flowchart of the ADC interrupt;

Fig. 15 is a **computer** program flowchart of the CHECK BLOWER SPEED subroutine;

Fig. 16 is an electrical block diagram illustrating the spectral sound analysis circuit;

Fig. 17 is a computer program flowchart of the SOUND ANALYSIS subroutine;

Fig. 18 is a schematic block diagram of...

...airway flow, pressure and admittance, and further illustrating two admittance templates;

Fig. 20 is a **computer** program flowchart for operating the microcontroller of Fig. 18; and

Fig. 21 is a **computer** program flowchart of another program embodiment for operating the microcontroller of Fig. 18. Fig. 22...

...the electronic components associated with the compensation embodiment of Fig. 22;

Fig. 24 is a **computer** program flowchart of the PRIMARY module for operating the compensation embodiment;

Fig. 25 is a **computer** program flowchart of the INITIALIZE module of the PRIMARY module;

Fig. 26 is a **computer** program flowchart of the EXHALE module of the PRIMARY module;

Fig. 27 is a **computer** program flowchart of the INHALE module of the PRIMARY module;

Fig. 28 is a **computer** program flowchart of the **CPAP** BACKUP module of the PRIMARY module;

Fig. 29 is a **computer** program flowchart of the BPM CYCLE BACKUP module of the PRIMARY module;

Fig. 30 is a **computer** program flowchart of the PATIENT CYCLE BACKUP module of the PRIMARY module;

Fig. 31A is a **computer** program flowchart of the first portion of the A/D INTERRUPT module of the PRIMARY module; and

Fig. 31B is a computer program flowchart of the remaining portion of

the A/D INTERRUPT module.

Detailed Description of...pillow 14 on the head of patient 36 in order to fluidically couple with the respiratory passages of patient 36, and preferably with the patient's nares. Nasal pillow 14 is...microcontroller 802 (Intel Type 8097BH), programmable array logic (PAL) (Type PC16L8), erasable, programmable, read-only-memory (EPROM) (Type 27256), address latch 808 (Type 74HC373), random access memory (RAM) (Type 6264P), input/output serial data interface (RS232 Type MAX232), prescription (RX) switch array 814...802 for data and address information flow with PAL 804, EPROM 806, address latch 808, RAM 810, and data latch 816 at the terminals as shown in Fig. 8. Fig. 8...and terminals 1, 8, and 15 are all connected to ground.

Figs. 11-14 are **computer** program flowcharts illustrating the operative program for microcontroller 802.

- Fig. 11 illustrates the START-UP portion of the main routine of the computer program for operating microcontroller 802. After the logic low reset signal goes logic high, the...and read by way of address data bus 830. These values are then stored in RAM . Step 1104 also prompts microcontroller 802 to set the operating speed of blower motor 904...
- ...step also defines the start-up mode of the apparatus as continuous positive airway pressure (CPAP). That is to say, and as explained further hereinbelow, the program operates apparatus 10 in...of operation is set for inspiratory nasal air pressure (INAP). This was initialized in the CPAP mode in step 1112. During the first eight breathing cycle, the answer in step 1226...to step 1314 which retrieves the step pattern for the next blower motor step from memory. The program then activates the lines of bus 832 in order to send this step...
- ...the pressure data received from pressure transducer circuit 700, and to store this data in **memory** . Subroutine 1400 enters at step 1402 which retrieves the current data from the ADC register...conversion to produce digital data representative of the three spectrum components.

Fig. 17 is a **com**puter program flowchart of SOUND ANALYSIS subroutine 1700 which is advantageously included as part of the...

...should be taken concerning the increase or decrease of the gas pressure applied to the **respiratory** passages of the patient. This determination occurs in step 1722 by use of a so-called "action table" which is a look-up table stored in **memory** using variable T as a pointer. The preferred action table is incorporated as part of...properly characterized and aspects of the respiration quantified.

Furthermore, this information can be stored in **memory** for subsequent downloading for use by a physician, for example, in diagnosing **respiratory** afflictions and efficacy of treatment. In this way the expense and time consumed in sleep...

- ...treating many conditions in which facilitated respiration is a factor in treatment. For example, increased **respiratory** air pressure beginning just prior to inhalation induces a deeper inhalation than might otherwise occur...
- ...means for patient coupling in order to impose the higher breathable gas pressure on the **respiratory** passages of the patient. The present invention, however, also encompasses a nasal mask, or a...
- ...to increase or decrease the pressure of the breathable gas applied to the patient's respiratory passages. As the detailed description reveals, however, the apparatus hereof includes the capability of varying

...example.

As described above, the preferred controller includes microcontroller 802 which is operated by a **computer** program. Other equivalent control means might include a custom designed chip with all functions implemented in hardware without a **computer** program.

As disclosed in Fig. 6 herein and the accompanying narrative

As disclosed in Fig. 6 herein and the accompanying narrative description, it is preferred...thereby determining admittance, such problems are avoided.

As explained further hereinbelow in connection with the **computer** program flowchart of Fig. 21, it may be desirable to eliminate divider 1812 in certain...

- ...the inhalation portion of a single breath cycle is compared to admittance templates stored in **memory** to determine which template provides the "best fit" with the latest admittance plot. The best...
- ...such as raising or lowering gas pressure delivered to the patient.
 Fig. 20 illustrates a computer program flowchart of subroutine 2000 for operating microcontroller 802 of the embodiment shown in Fig...
 ...the differences between the corresponding data points in array "A" and each template stored in memory according to the formula shown.
 The program then moves to step 2010 which determines which...
- ...pressure, from a look-up table such as that illustrated below:

 Fig. 21 is a computer program flowchart of module 2100 for operating microcontroller 802 in the embodiment of Fig. 18...
- ...airway patency is effectively quantified. That is to say, the set of templates stored in **memory** could represent a range of patencies (in percentages, for example) and the best-fit template...
- ...advantageous to continuously update the set of templates by storing successive admittance array data in **memory** as a new template. Additionally, certain templates could be designated as templates characteristic of wakefulness...predetermined time based upon a fixed time or based upon previous breathing patterns the preferred **breathing** device activates the electrodes to stimulate the upper airway muscles. In this way, apneic episodes are...
- ...controlling and operating pneumatic system 70 of this embodiment. Controller 20 includes power supply 80, microprocessor 81, microprocessor memory 82, analog to digital (A/D) conversion circuitry 83, interface circuitry 84, serial communication port...
- ...and display control 87 with keyboard display panel 88 connected thereto.
 - Figs. 24 31B are computer program flowcharts illustrating the operation of the program stored in memory 82 for operating microprocessor 81 and thereby for operating ...variables indicated to their initial values as shown. Step 2504 then sets the pressure control mode to inhale and step 2506 clears the control mode flag indicating that the control mode has not been set.

 Steps 2508 and 2510 then...
- ... The phase control flags are then reset in step 2606 and the blanking interval counter **cleared** in step 2608. The **program** then returns to the PRIMARY module.
 - Fig. 27 illustrates INHALE module 2700 which is entered...

- ...it inhalation is not detected within a time limit based on breath rate. In the CPAP mode (Fig. 28), the pressure is increased to a constant value and maintained. In the...
- ...breath rates, or when exhalation is sensed, whichever occurs first.

 Turning first to Fig. 28, CPAP BACKUP module 2800 enters at step 2802 which asks whether the backup test is true...module 3000 which enters at step 3002. This step asks whether the backup flag is clear and if yes, the program moves to step 3004 which asks whether the inhale timer count is greater than or...
- ...sensor value. This value is then linearized according to look-up table values stored in **memory** which are empirically developed for the particular patient pneumatic hose 26 being used. In practice...answer in step 3138 is yes, step 3140 sets the Prx which is the control **mode** to inhale. Step 3142 then **clears** the blank interval counter, step 3144 saves the current sample count and step 3146 clears...
- ...CLAIMS processing means (802) for receiving the signals and responsive thereto for determining the patient's **respiratory** admittance from the substantially simultaneous flow and pressure; and means (20) for controlling the pressure...
- ...means for storing at least one admittance template composed of a plurality of admittances in **memory**, means for storing a set of the patient admittances, and means for comparing the admittance...
- ...bases, the controlling means including means for normalizing the amplitude and time base of the **respiratory** admittance in accordance with the stored templates.
 - 10. Apparatus as claimed in claim 7, in which the controlling means includes **memory** means for storing pressure change data in association with each of the templates, the controlling...
- ...as claimed in claim 1 or claim 7, in which the controlling means includes a microprocessor (802).
 - 13. Apparatus as claimed in claim 1, in which the signal processing means (802...
- ...the flows and pressures and storing admittance data representative of the admittance set in a **memory** device, and using the signal processing means for determining the admittances as the dividend of ...
- ...by pressure;
 - comparing in the signal processing means the admittance data with predetermined admittance templates stored in the memory device
 - determining in the signal processing means the closest match of the admittance templates with...

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(Item 108 from file: 349)
DIALOG(R) File 349: PCT FULLTEXT
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            **Image available**
 VENTILATOR CONTROL SYSTEM AND METHOD
SYSTEME DE VENTILATEUR PERMETTANT DE SEVRER AUTOMATIQUEMENT UN PATIENT DE
    SA VENTILATION MECANIQUE ET TECHNIQUE A CET EFFET
Patent Applicant/Assignee:
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    , US (Residence), US (Nationality)
Inventor(s):
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 VENTILATOR CONTROL SYSTEM AND METHOD
Main International Patent Class: A61M-016/00
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Fulltext Availability:
  Detailed Description
  Claims
English Abstract
  A patient ventilator system for automatically weaning a patient from a
  ventilator .
Detailed Description
  A SYSTEM FOR AUTOMATICALLY WEANING
  A PATIENT FROM A VENTILATOR , AND METHOD THEREOF
  Cross Reference to Related Applicatio
  [00011 This application is a continuation-in...
...160.
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[00021 The invention relates generally to the field of medical

specifically, to the control of such ventilators . @

Field of the Invention

ventilators or, more

Background of the Invention [00031 A medical ventilator delivers gas to a patient's respiratory tract and is often required when the patient is unable to maintain adequate ventilation. Mechanical ventilation is the single most important therapeutic modality in the care of critically ill patients. K'nown ventilators typically include a pneumatic system that delivers and extracts gas pressure, flow and volume characteristics...

...as the condition of the patient changes. Such adjustments, although highly desirable, are difficult to implement with Imown ventilators because the control system demands continuous attention and interaction from the clinician.

[00041 Further, patients requiring **ventilatory** assistance must overcome airway resistance in the breathing circuit during exhalation. This resistance, combined with...

...by underlying disease processes.

Summary of the Invention 100051 The invention relates to a medical mechanical ventilator device adapted for use in weaning a patient from mechanical ventilation. In one embodiment, the device measures the patient's minute volume, breath frequency, and detects a patient's spontaneous breath. The device compares the patient's minute volume and the patient breath rate to a predetermined minute...

...the period of at least two breaths.

[00061 In another embodiment, the invention is a ventilator system adapted for use in weaning a patient from mechanical ventilation. The ventilator system comprises a pressure 1 5 source in communication with the patient's respiratory system to provide pressure support to the patient. The device further comprises a breath frequency monitor, a minute volume now meter, an input device, and a data processing unit. The data processing unit compares the patient's breathing fi-equency and patient's minute volume to the breathing frequency and minute volume entered by the clinician. Pressure support is adjusted by the ventilator on an intrabreath or interbreath basis.

Brief Descriptions of the Drawings [00071 FIG. I is a block diagram of an embodiment of a **ventilator** of the invention.

- [0008] FIG. 2 is a detailed block diagram of a display controller...
- ...diagram of an embedded controller.
- [0010] FIG. 4 is a detailed block diagram of a **ventilator** pneumatic unit.
- [00111 FIG. 5 is a diagram illustrating an embodiment of the adjustment of...
- ...0012] FIG. 6 is psuedocode of an embodiment of a triggering algorithm used by the **ventilator** of the invention.
 - [0013] FIG. 6a is a pressure and flow diagram of the patient...
- ...patient ventilation triggering.

[00141 FIG. 7 is an illustration of a display screen when the **ventilator** control system is in the operational mode.

[00151 FIG. 8 is an illustration of a...

...FIG. I I is a flow chart of the data structure hierarchy employed by the **ventilator** control system.

[0019] FIG. 12 is an embodiment of a flow chart of an exhalation...

...invention.

[00201 FIG. 13 is an illustration of a simulation mode display screen for the ${\bf ventilator}$ control system.

[00211 FIG. 14 is a functional block diagram of the simulator portion of the ${\bf ventilator}$

control system

[00221 FIG. 15 is an illustration of a section of the display screening \dots

...waveform shaper.

[0023] FIG. 16 is an illustration of a therapy programming screen for the **ventilator** control system.

[00241 FIG. 17 is a flow chart for automatic weaning of a patient from a ventilator according to an embodiment of the invention.

Detailed Description of the Invention

[00251 1. Ventilator Control System - The invention features a ventilator control system for controlling a ventilator pneumatic system in. a medical ventilator. The ventilator control system provides a clinician with complete control of a patient's airway flow and pressure throughout the respiratory cycle, and thereby enables the clinician to determine the optimal therapy for the patient. In...

...this situation, negative pressure can be applied to the exhalation circuit of the patient's **ventilator** to reduce the ...100271 If airway pressure rises above the clinically indicated level of positive end-expiratory pressure (**PEEP**), the lung will be overpressurized thus the effective airway pressure throughout the expiratory cycle is titrated throughout the expiratory phase under precise algorithmic control.

The clinical benefit of a certain $\mbox{\bf PEEP}$ level will be diminished. Thus, the effective airway pressure throughout the expiratory cycle must remain greater than zero and less than $\mbox{\bf PEEP}$.

[00281 FIG. 1 is a block diagram of a **ventilator** including a **ventilator** control system IO incorporating the features of the invention. The **ventilator** control system IO includes a display controller 12 and an embedded controller 14. The display...

...interface to the clinician 16, and the embedded controller 14 provides an interface with a ventilator 17 providing ventilation to a patient 20. The display controller 12 and the embedded controller 14 each include memory (not shown) and are electrically coupled via a shared memory interface 15.

Data from the display controller 12 and the embedded controller 14 are stored...

...embedded controller 14 to calculate the amount of negative pressure to

be generated in the **ventilator** 17 in order to produce an airway pressure greater than zero and less than positive...

- ...gas delivered from the source of pressurized gas 45 through a Venturi valve within the **ventilator** 17 to produce this negative pressure. One embodiment of such a pneumatic system 41 is...
- ...by reference. A pressure sensor 51 measures the amount of negative pressure produced within the **ventilator** 17 and transmits these data to the embedded controller 14. These data are stored in...
- ...controller 12. Each of these target values is compared with a corresponding current value of **ventilatory** unit pressure, airway pressure, airway flow and airway resistance by the embedded controller 14. Upon...
- ...so that the pneumatic system 41 changes the amount of negative pressure produced by the **ventilator** 17. The **ventilator** 17 is in pneumatic comraunication with a flexible tubing 21 capable of attachment to a...
- ...serial number 08/352,659, kicorporated herein by reference.
 - [0033] The safe performance of the **ventilator** IO is enhanced by the redundancy of the two independent display controller 22 and embedded controller 30 processors, which continually check each other's performance via the shared **memory** interface 15. The embedded controller 14 communicates its status, and that of the patient, to...
- ...the last known good settings if communication becomes lost. The two systems which comprise the **ventilator** control system 10 give both audible and visual messages when an alarm condition exists, and...
- ...absence of breathing). During operation, both systems perform background tests to detect system faults. The **ventilator** provides a series of reduced bperation modes to provide life support if system capability is ...flexible means to change control settings.
 - [00351 The display controller 12 is a powerful graphics workstation with hardware and software components. In one embodiment, the clinician interacts with the display controller...
- ...to the monitor. In one embodiment, the processor 22 is included in a single board **computer** which also includes **RAM**, an integrated high speed graphics driver, and an integrated dual port **memory**.

The display controller 12 also includes a hard disk drive 23.

[00361 While the display controller 12 provides interpretation and decision support information on the display 24, the **ventilator** 17 does not change any breath control parameters unless directed by the clinician 16. Nevertheless, the display controller 12 provides a flexible **user interface** with multiple interactive levels, from simple text menus of controls for inexperienced users, to complete...

...embedded controller 14 includes a system board 28, a real time data processor 30, a **ventilator** processor 32 and an airway processor 31.

The real time processor 30 manages sensor...

...system 19, processes measured data, performs alarm/fault detection and provides control data to the **ventilator** 17. The embedded controller 14

- further receives data input by the clinician 16 and accesses...
 ...system 19 relating to airway pressure, flow and resistance. A second data processor 32, a ventilatory unit processor, receives signals from the pressure sensor 51 in communication with the ventilatory pneumatic system 18. Signals from both data processors 31 and 32 are transmitted to a...
- ...to airway pressure, flow and resistance to preselected values and then calculating the change in **ventilatory** unit negative pressure required to affect the desired change in airway resistance.
 - [00391 In more detail, and referring also to FIG. 4, a block diagram of the **ventilator** 17 in communication with the flexible airway 21 that is the conduit for inhalation from...
- ...airway 21 to assist the patient's exhalation through the canister 49 into the medical **ventilator** 7. Pressure within the flexible canister 49 is measured by a press-Lire sensor 5...

...14.

- [00401 Now referring also to FIG. 5 a detailed functional block diagram of the **ventilator** control system 10 is depicted. As shown, the clinician 16 manipulates a control setting slider...
- ...the clinician's inputs and creating 40 a breath control structure which is stored in **memory**. The display controller 12 transmits the breath control structure to the embedded controller 14 and...
- ...panel 36. The embedded controller 14 initially stores 44 the breath control structure in local memory. The ...14 re-validates 46 the settings within the breath control structure. The embedded controller 14 implements 48 the validated breath control structure 48 using a breath control algorithm 50 and provides signals to the pneumatic...
- ...panel 36 to the cause of the error and the process is terminated.
 - [0041] The **ventilator** control system IO provides two independent feedback paths to assure the clinician 16 that his...
- ...displays 60 a, series of measurements (e.g., peak airway pressure, peak airway flow, and **PEEP**) from the waveform data both numerically and graphically. Second, the display controller 12 displays 54...
- ...embedded controller 14 and passed directly to the display 24.
 100421 One feature of the **ventilator** control system 1 0 is that it can be configured to provide an assisted phase...
- ...the accumulated volume of gas inhaled by the patient as a result of his spontaneous respiratory muscle activity can be monitored. To accomplish this, the sensor monitoring system 19 measures the...
- ...volume dynamically according to measured patient flow and pressure signals indicating the phase of the **respiratory** cycle. In particular, the embedded controller 14 may increase the trigger volume set by the...
- ...system 41, and not by spontaneous efforts of the patient.
 - 100431 Another feature of the **ventilator** control system is its ability to distinguish between active inspiratory effort and passive reverse

airflow...

...until the trigger volume has been reached (Steps 320, 330).

[0046] Another feature of the **ventilator** control system is its ability to compensate for gas flow resistance into and out of...

...input device 26, the clinician 16 call set a resistance parameter of the patient's respiratory system to a selected value.

Alternatively, the display controller 12 may calculate a value for...

- ...row of touch sensitive oil/off buttons 66 includes: a Power button that controls the **ventilator** control system; a Freeze button to pause the display; a Modes button to display various...
- ...play back a database of historical patient protocols; a 100% 02 button to flush the **ventilator** with oxygen; Help and Save buttons; and an Others button to display other capabilities.

[00491 The left side of the screen includes a list of the publicly available ventilator control settings. ...and partially controlled by the patient, and mandatory breaths, those triggered and controlled by the ventilator . The ratio of the colored areas indicates the ratio of spontaneous to mandatory breathing during...

...13 the clinician selects a phase of a waveforin, the display controller displays the associated **ventilator** controls for available for adjustment by the clinician.

[0056] The display controller provides cursors- 201 waveforin values, positioning based on **user interface** gestures.

[00571 The background of the waveform (74, 76) includes color shading to indicate breath...

...and scale information. Redrawing these graphics as new waveform samples are displayed generally requires substantial **computer** time, and the display controller performs this function efficiently notwithstanding the complexity of the background...

microprocessor 32 is in electrical communication-with the ventilatory

- ...Peak Inspiratory Pressure 2 to 120 cmH20 Exhalation Assist 0 to 30 cmH20/L/sec PEEP 0 to 20 CMH20 Inspiratory Time 0.2 to 4 see Inspiratory Pause Time 0...
- ...to 120 Urnin
 Oxygen Percentage 21 to 100%
 Peak Inspiratory Pressure 0 to 120 cmH20
 PEEP 0 to 20 cmH20
 Mean Airway Pressure 0 to 120 cmH20
 Inspiratory Time 0.1...
- ...Alarms and Indicators
 High/Low Exhaled Tidal Volume Alarm 50 to 2000 niL
 High/Low Respiratory Rate Alarm 2 to 150 bpm
 Low Oxygen Fresh Gas Flow Automatic, % 02
 dependent
 Low...Embedded Controller Referring again to FIG. 1, the embedded controller electronics 14 is based around microprocessors 31, 32. The

- unit 17 and the **microprocessor** 31 is in electrical communication with the sensor monitoring system 19. The embedded controller relies...
- ...custom printed circuit boards to perform other functions. The modules, the printed circuit boards, the **ventilatory** unit pressure processors 32 and the airway processor 31 are mounted on or connected to...
- ...and provides battery backup for a average of one hour. The embedded controller 14 has **microprocessor** and associated input/output hardware to provide for closed loop control of pneumatic system 41...

...Gas.

[0071] The embedded controller 14 communicates with the display controller 12 via a shared **memory** interface 15 at a data transmission rate exceeding 1 OOK bytes per second.

[00721 4...

- ...FIGS. I and I 1, the figures illustrate the data structure hierarchy for the 5 **ventilator** control system. Using an input device 26 such as the touch-sensitive display 24 within...
- ...13. In any case, the clinician 16 sends the new therapy control structure to the **memory** for use by the embedded controller 14 in controlling the pneumatic system 41. A therapy...A phase control structure 150 (or a cycle control) is defined as a collection of **ventilator** control settings 154 and an array of waveform. samples 156. Phase definitions and requirements for...
- ...to measurable system performance, and correlate closely to published descriptions of the desired behavior of **mechanical ventilators** .
 - 19 [00741 More specifically, the therapy control structure 140 is a nested hierarchy of increasingly...
- ...control, which occurs within therapy control, which is the clinically specified therapy that drives the **ventilator** pneumatic system 4 1. Once each cycle, ventilation control moves from one control state to...
- ...from an inspiration phase to a pause phase to an exhalation assist phase to a **PEEP** phase, but these phases may be further subdivided for a finer granularity of control.

- 20...

- ...Within a phase, within a breath, within a mode, within a therapy, there is a **ventilator** control setting structure 154. This structure contains an array of samples that comprise a specified...
- ...is driven by the waveform sample specific for the cycle, and by a collection of **ventilator** control settings 154 specific for the phase. The cycle time is in milliseconds, and is...
- ...may be specified by the clinician and take control at the next cycle.
- [0080] Each ventilator control setting structure 1 5 8 contains necessary and sufficient information to control one parameter...
 ...adjusted automatically within the specified range. Each phase control structure has its own collection of ventilator control settings, although in practice, phases within a breath generally share the same collection.

100811...

- ...of hazardous conditions by permitting non-programmers to review and understand the fariction of the **ventilator** control system.
 - [0082] Several breath control structures are predefined in the embedded controller. These breath...clinician 16 entering the desired values relating to airway resistance or negative pressure in the ventilatory unit (Step 1). These values are then compared with data relating to airway resistance or negative pressure in the ventilatory unit that have been measured or calculated by the data processing unit (Step 2). It is then determined whether these sets of data are equal to each...
- ...7). It is then determined whether airway pressure is greater than zero and less than PEEP (Step 8). If airway pressure is greater than zero and less than PEEP, airway resistance is calculated and pressure in the ventilatory unit is measured (Step 9). After these measurements and calculations are made, the cycle recommences (Step 2). If airway pressure is not greater than zero and less than PEEP, it is determined whether the alarm has been overridden (Step IO). If the alarm has...
- ...the status of the patienfs pulmonary system. The simulator 212 simulates the adjustment to the **ventilator** pneumatic system 41 in response to the set of breath parameters and the response of...
- ...unaffected. When the 22 clinician 1 6 begins changing settings in the simulation mode, the **ventilator** control system 1 0 predicts the effects of the change and displays the predicted result...
- ...and compliance to predict the effect. The model assumes no contribution from the patient's **respiratory** muscles (i.e., a passive inspiration and exhalation cycle). The model used is.

Airway Pressure...

- ... Airway Flow x Airway Resistance).
 - I 0 [00861 A change in patient intervention in current **ventilators** typically requires multiple setting changes. Implementing such setting changes is greatly complicated by the series...
- ...background. Other controls are listed as active or inactive. The explicit list of active controls clearly delineates the exact function of the mode and alleviates confusion caused by inconsistent or incomplete definitions. Moreover, the simulator 212 can precisely replicate the behavior of modes on preexisting ventilators. The clinician 16 can make adjustments to the list of controls to accurately simulate the ventilator that a hospital's staff has been trained to use.

The list of controls together...

- ...simulated behavior can help teach the effects of various modes on patients, rather than the **ventilator** -specific mode definition.
 - Pi 1 [00881 As claimed in FIG. 13, while the simulator 212...a touch zone on the display 24. The processor 22copies the selected patient protocol into memory . In the operational mode, the processor 22 instructs the

embedded controller 14 to simultaneously adjust...

...protocol. In the simulation mode, the 1 5 simulator 212 simulates the adjustment to the **ventilator** pneumatic system 41 and the resulting response of the patient's pulmonary system.

[00911 The...

- ...00921 FIG. 14 is a detailed functional block diagram of the simulator feature of the **ventilator** control system 210. The clinician manipulates a control setting slider 216 to change or set a **ventilator** control setting. The clinician's input are stored in a **memory** 218. The simulator 220 receives the inputs and creates a phase control structure, a breath...
- ...24 therapy control structure) is transmitted to the embedded controller (at 224) via the shared **memory** interface. The embedded controller validates the settings within the breath control structure 226. The processor...
- ...data stream can be generated by sensors, which is the usual manner in which the **ventilator** operates, by the simulator 212 which uses the breath parameters and measured patient parameters to...
- ...to display real data, simulated data and epoch data is an important feature of the **ventilator** control system.
 - [0095] 9. Integrated Control/Data/Alarm. Display Referring again to FIG. 7, patient...panel of selected targets appropriate for the range, and which, if enabled, means that the **ventilator** control system will seek to accomplish a range target goal 213 by varying the control...
- ...trigger for the transition fi-om variable pressure support (VPS) to assist control (A/C pc) is minute volume (MV), while the trigger for the transition from assist control to variable...
- ...the patient, with much more power and flexibility than selecting from a set of simple **ventilator** modes preset by the manufacturer.
 - 27 [01031 1 1. In another aspect, the $\mbox{ventilator}$, according to the invention, operates using several mode control structures in a paired configuration, which...
- ...Support-Variable Pressure Control (VPS-VPC), and Continuous Positive Airway Pressure-Assist Control/Pressure Control (CPAP -A/C/pe). The primary mode control structure provides support to a spontaneously breathing patient. The secondary mode control structure is a mode control structure in which the ventilator provides Rill support to the patient with mandatory breaths. The mode transition trigger for switching...
- ...In one embodiment, the clinician sets a minute volume threshold, which allows the patient and **respiratory** patterns to control whether the primary or secondary mode control structure is still active. If VPC, a secondary control mode structure.

APS automates weaning of the patient from a **ventilator** and protects against patient **respiratory** failure indicated by the patient's increasing **respiratory** rate.

[0105] In a typical clinical setting, progressive withdrawal, i.e., weaning of a patient...

- ...VPC to obviate the necessity of frequent clinician interventions and prolonged clinician involvement with the **ventilator** weaning process. This automates the weaning of a patient from a **ventilator**. In VPC, the operating pressure range for ventilating a patient is set. The **ventilator** continuously adjusts the pressure in order to provide a minimum pressure required to deliver a 28 set tidal vol-ame. A breathing rate is set andthe **ventilator** delivers mandatory breaths to maintain the minimum breathing rate. The patient may initiate breaths above...
- ...set breath rate by exerting a minimum effort, as set by the clinician, and the **ventilator** will provide the pressure support required to deliver the set tidal volume. The set tidal...
- ...the clinician. When the patient's minute volume is below the set MVT level, the **ventilator** remains in VPC. When the patient exerts enough effort to drive the minute volume above...
- ...the breathing rate is below the lower alarm limit. If either or both occur, the **ventilator** is triggered back into VPC mode.
 - 1 5 [01081 In the APS-VPC embodiment for weaning a patient from a ventilator described herein, the initial pressure support level is determined by assigning the current VPC pressure support level of the patient and ventilator in the VPC mode, as the initial pressure support level for APS. This ensures a smooth transition for the patient and removes the guesswork- and the lengthy process of determining the pressure support level by the clinician to begin weaning of the patient fi-om the ventilator. In the APS-VPC mode, the patient's effort in VPC mode determines the initial...
- ...be reduced.

The effect is to automate the weaning process with an automatic withdrawal of **mechanical ventilation** using a closed loop control for pressure support.

- 29 [01101 Another feature of the APS...
- ...0111J In the AP`S-VPC mode, the MVT level must be reached for the ventilator to switch between the APS mode and the VPC mode. For example, if the patient' minute volume (MV) is 1 0 below the MVT trigger, the ventilator remains in VPC, when the patient's MV is above the MVT level, the ventilator switches to APS mode when the patient breathes spontaneously.
 - [01121 In addition to monitoring and...
- ...limit (described below), Low Pressure Alarm Level, MVT, and Breath Rate Range. The patient begins **breathing** while the **ventilator machine** is in control mode VPC (Step 420). The starting pressure support (PS) level in VPC...
- ...43 0) and the patient's minute volume is greater than MVT (Step 440), the **ventilator** is switched from VPC mode to APS (Step 450).
 - [01141 The AP S mode detects...
- ...0116] The PS-DECR is set during initial step 400 by the clinician on the ventilator control panel.

The PS-DECRisa Rate % decrement ranging from 0.01% to 0.1%. In one embodiment, the clinician sets the Rate % decrement...

...clinician in Step 400.

Thus, the automatic weaning process is accomplished by automatic withdrawal of mechanical ventilation using a closed loop control for APS.

[0117] The patient's spontaneous breathing rate is...

Claim

CLAIMS

- 1 A method for automatically weaning a patient from a $\ensuremath{\mathbf{ventilator}}$, the method
- comprising the steps of:
- (a) providing pressure support to a patient;
- (b) detecting...
- ...to the predetermined minute volume.
 - 2 The method for automatically weaning a patient from the **ventilator** of claim 1, the method ftu-ther comprising the step of. (h) decreasing the patient...
- ...exceeds the predetermined minute volume.
 - 3 The method for automatically weaning a patient from the **ventilator** of claim 1, the method ftirther comprising the step of(h) increasing the patient's...
- ...method of claim I further comprising adjusting the amount of pressure support between zero and **PEEP** . 5 . The method of claim 1 wherein the patient's pressure support level is decreased...
- \ldots from patient's spontaneous breath rate to obtain the patient's breath rate.
 - $8\ \mbox{\ensuremath{A}}$ $\mbox{\ensuremath{\mbox{\ensuremath{ventilator}}}$ system for automatically weaning a patient from a $\mbox{\ensuremath{\mbox{\ensuremath{\mbox{\ensuremath{a}}}}}$ and the system of t

comprising:

- a source of pressure in communication with the patient to provide pressure support to...
- ...rate range and a predetermined minute tidal volume;
 - a minute volume flow meter; and
 - a data processing unit in electrical communication with said pressure source, said breathing rate. monitor, said flow meter, and said input device, wherein, said data processing unit I I calculates an average breath rate and a current breath rate from a signal...
- ...and adjusts the pressure source to change pressure support in response 5 thereto.
 - 9 The **ventilator** system of claim 8 wherein said source of pressure comprises a pneumatic system comprising a...
- ...pressurized gas, a rigid chamber, a flexible chamber and a Venturi valve. I 10. The **ventilator** system of claim 9 finther comprising a high

speed pneumatically driven, electronically controlled proportional valve and dual Venturi systems. I 11. The **ventilator** system of claim 8 wherein said input device is a touch screen in electrical communication with a display controller processor.

- 12 The ventilator system of claim 8 wherein said data processing unit is a real time data processor in electrical communication with a ventilatory unit processor and an airway processor.
- 13 A method for automatically weaning a patient from a ventilator , the method comprising the steps of: providing pressure support to the patient; determining the patient...

(Item 114 from file: 349) 32/3,K/114 DIALOG(R) File 349: PCT FULLTEXT (c) 2004 WIPO/Univentio. All rts. reserv. **Image available** SYSTEM AND METHOD FOR UPGRADING A MEDICAL DEVICE SYSTEME ET PROCEDE DE MISE A NIVEAU D'UN DISPOSITIF MEDICAL Patent Applicant/Assignee: RESPIRONICS INC, 1010 Murry Ridge Lane, Murrysville, PA 15668, US, US (Residence), US (Nationality) PAWLIKOWSKI James, 114 Third Street, Aspinwall, PA 15215, US, SHISSLER Andrew L, 124 Rock Springs Drive, Delmont, PA 15626, US, KANE Michael T, 320 Dogwood Drive, Delmont, PA 15626, US, DUFF Winslow K, 3230 New England Lane, Export, PA 15632, US, Legal Representative: GASTINEAU Cheryl L (et al) (agent), Reed Smith, LLP, P.O. Box 488, Pittsburgh, PA 15230-0488, US, Patent and Priority Information (Country, Number, Date): Patent: WO 200249259 A2-A3 20020620 (WO 0249259) Application: WO 2001US48413 20011213 (PCT/WO US0148413) Priority Application: US 2000256021 20001215; US 200116506 20011210 Designated States: (Protection type is "patent" unless otherwise stated - for applications prior to 2004) AU BR CA JP S DEC (EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR Publication Language: English Filing Language: English Fulltext Word Count: 14260 Fulltext Availability: Detailed Description

English Abstract

Claims

... operating routine executed by the controller (48). Upgrading the medical device (32) includes communicating an external device such as a conventional computer , with the controller. An external access key is provided to the external device and compared to an internal access key provided by the medical device (32). Upgrading of...

...enabled if the two access keys match. Upgrading includes modifying or rewriting the operating routine stored in the medical device (32). A medical device (32) manufacturer, supplier, or seller controls the distribution of the external...

Detailed Description

... the medical devices to be recalled.

If a medical device uses a programmable read-only memory (PROM) to store the operating routine, upgrading the operating features of that device is very...

- ...the unit and physically replace the PROM with an upgraded PROM or other upgraded data storage device . Although this process is burdensome and requires that the patient forgo the use of the...
- ...devices and their upgraded status.

If the medical device uses an erasable programmable read-only memory (EPROM) to store the operating routine, also referred to as a flash memory, the device can be upgraded without disassembling the unit. Instead, reprogramming the EPROM can be done using any conventional reprogramming technique via a data port, which is typically provided on the external surface of the housing. While, this significantly...

- ...in the field, can be done by the medical device provider/dealer, if the medical device uses an EPROM storage, and if the manufacturer, supplier, or seller provides the upgraded operating routine to the medical...
- ...to treat a medical disorder. One such system, known as a continuous positive airway pressure (CPAP) device, supplies a flow of breathing gas at a constant positive pressure to the airway...
- ...OSA), cheynes-stokes respiration, congestive heart failure, central sleep apnea, as well as other cardio- respiratory disorders.

The ability of a pressure support system to provide a continuous pressure, as opposed...

- ...operating feature of the system that is determined at the time of manufacture. The specific CPAP pressure that the device is to deliver, which is typically not set when the device...
- ...P pressure is set to a prescription level once a patient has been prescribed the CPAP device.

Setting the CPAP pressure is accomplished, for example, by manually setting a switch, dial, knob or other input device associated with the medical device. If the CPAP operates according an operating routine stored on an EPROM, setting the CPAP pressure can be accomplished by downloading the CPAP pressure as an operating feature directly into the controller or the memory of the medical device via a dedicated RS232 port.

A conventional **ventilator**, such as the ESPRITO **Ventilator** manufactured by Respironics of Pittsburgh, PA, is an example of a pressure support system in...

...that delivers a flow of breathing gas to the airway of a patient, including a **ventilator** .

A conventional ventilator is capable of operating in a variety of ventilatory modes, where each mode corresponds to a different technique by which & ventilator controls its four basic ventilator operations. These four basic operations are: 1) determining of the trigger point, which is the transition from the expiratory to the inspiratory phase of the ventilatory cycle, 2) controlling the ventilator during the inspiratory phase where the ventilator delivers the flow of breathing gas, 3) determining the cycle point, which is the transition from the inspiratory phase to the expiratory phase, and 4) controlling the ventilator during the expiratory phase.

What the **ventilator** does in each mode of ventilation is typically determined at the time of manufacture, so that the **ventilator** always operates the same way each time a particular **ventilatory** mode is selected. However, which **ventilatory** mode the **ventilator** is to operate in, and the particular parameters of that mode, are generally not

set when the **ventilator** leaves the factory. These operating features are set by the caregiver based on the needs of the patient when the patient begins using the **ventilator**. What the **ventilator** does in each **ventilator** mode, the selection of which mode to operate in, and the selectable parameters associated with each mode are considered the operating features of the **ventilator** for present purposes.

It is known to provide a pressure support device in which the...

...level" pressure support.

With bi-level pressure support, the patient's inspiratory positive airway pressure (IPAP), expiratory positive airway pressure (EPAP), and how the device detects and compensates for system leaks...

- ...to the patient based on whether or not the patient is snoring is the Virtuosoo CPAP family of devices manufactured and distributed by Respironics, Inc. This auto-titration pressure support mode...
- ...could occur and adjusts the pressure output to avoid this result is the TranquilityO Auto CPAP device, also manufactured and distributed by Respironics, Inc. This auto-titration pressure support mode is...
- ...pressure support device capable of operating in a PAV mode. Proportional positive airway pressure (PPAP) devices deliver breathing gas to the patient based on the flow generated by the patient. U.S. Patent... However, instead of receiving medicine, the patient receives a durable medical product, such as a CPAP device, to treat his or her condition. As with a medication prescription, the patient's...
- ...device, such as alarms, the ability to provide a time backup breath, which is a **ventilatory** breath that is delivered to the patient if he or she does not spontaneously initiate...
- ...support treatment or mode provided to the patient by the pressure support system, e.g., CPAP, bi-level, auto-titration, PPAP, PAV, or a combination thereof. While a great number of...
- ...the system. For example, a typical bi-level pressure support system can operate as a CPAP device if the IPAP and EPAP levels are the same. As noted above, a conventional ventilator is also typically capable of operating in one of several ventilatory modes.

Once a patient is prescribed a pressure support treatment, to minimize $\cos t$, he or...

- ...device capable of delivering bi-level pressure support to a patient who needs only a CPAP pressure support therapy, especially since the patient may need to be switched to a bi...
- ...It is also not uncommon for an OSA sufferer to initially be treated with a CPAP device, and, thereafter, switched to a bi-level device in order to increase their comfort...
- ...be delivered to the patient. However, other than operating the bi-level device as a CPAP device, as discussed above, changing the bi-level device to any other mode of pressureThe method further includes providing an external device that communicates with the controller, establishing a communication link between the external device and the controller, and inputting an external access key to the external device. The internal access key provided by the medical device is compared with the external access...

- ...the medical device according to an operating routine executed by the controller and (2) a **memory**, associated with the controller, that stores the operating routine. A set of operating features of...
- ...by the medical device is associated with each set of operating features of the medical device. An external device communicates with the controller via a communication link between the external device and the controller. The external device is also adapted to receive an external access key. The controller and external device communicate with one another so that controller or the external device can compare the internal access key with the external access key. If they match, upgrading...
- ...available to the medical device supplier, that includes the first product identifier for the medical **device** and an **external** access key associated with both the medical device and an available upgrade. The database is...
- ...to the medical device supplier. The database includes the first product identifier for the medical **device** and an **external** access key associated with both the medical device and an available upgrade. The method includes...
- ...the desired upgrade so that the upgrade requester can introduce the upgrade to the medical **device** if the **external** access key matches an internal access key associated with the medical device.

In addition, the...support system, that generates a flow of breathing gas at an elevated pressure, and an **external device** 34 that communicates with pressure support system 32 via a communication link 36 for the purpose of upgrading the medical device.

As discussed in greater detail below, external device 34 is preferably a conventional computer, such as a laptop or personal computer, that can be readily transported to the site where the medical device is located, such...

- ...medical system. Of course, the present invention also contemplates the opposite, i.e., bringing medical **device** to the **external device**. The present invention enables the processing components of medical device 32 to communicate with the **external device** for purposes of upgrading the operation of the medical device, for example, by downloading an...
- ...the medical device, either in addition to or in place of the existing operating routine **stored** in the medical **device**.

A manufacturer, supplier or seller of the medical device has the ability to control and...

...of each medical device under its control by limiting the ability to upgrade the medical **device** via the **external device**. According to the principles of the present invention, controlling and tracking the ability to upgrade...delivered to the patient.

For example, in a bi-level pressure support system, cycling from IPAP to EPAP and triggering from EPAP to IPAP are based on the changes in the patient's breathing cycle, which is detected by...

- ...support system. Still other external sensors can include EMG electrodes provided on the patient, a **respiratory** belt that measures movement of the chest and/or abdomen, and a motion sensor to...
- ...medical device are upgraded according to the principles of the present invention. In this embodiment, external device 34 includes a processing unit 68 that communicates with the medical device via a data port 70. External device also includes an input/output device 72 and the, ability to read data from a distribution medium 74, such as a floppy disk reader, a compact disc read only memory (CD-ROM) reader, tape drive or any other conventional data reading device. Of course, external device 34 can include other features typically associated with a conventional computer, such as an audio input, audio output, ports for communicating with external devices, such as a printer, modem or link to other communication systems via any conventional communication...48 is

accomplished by coupling a communication cable between a data port 70 in the **external device** and a data port 78 provided on the medical device for this purpose. In an...

...understood, however, that the present invention contemplates any conventional technique for exchanging data between the **external device** and the medical device including a hardwired or wireless communication link.

As schematically shown in Fig. 3, controller 48 in medical device 32 includes a memory 80, such as a flash memory or EPROM. In the illustrated exemplary embodiment of the present invention, memory 80 is segregated in to a plurality of memory sections 82, each of which is individually erasable so that the entire memory or portions thereof can be eased and rewritten. Memory 80 stores the operating routine that is executed by the controller 48 each time the...

...leaks, and triggering and cycling the pressure generating system.

In one of the sections of memory 80, or in a portion of a section, a plurality of access key memory locations 84 are allocated for storing a plurality of access keys, which are discussed in greater detail below. One embodiment of the present invention contemplates providing fifteen such access key memory locations, of course this number can be increased or decreased so long as there is at least one access key memory location.

In the illustrated embodiment, a first access key "xxx" is shown stored in a first access key memory location 86. The access keys of the present invention are preferably a sequence of alpha-numeric characters capable of being entered and processed by a conventional computer processing system. It is to be understood, however, that other characters can be used in...

...character sequence, including a single character.

While Fig. 3 illustrates the remaining fourteen access key **memory** locations as being empty, it is to be understood that a default access key or...

...of the medical device are determined based on the operating routine that is stored in **memory** 80. In addition, an access key is associated with each set of operating features of...

- ...In effect, an access key is associated with each operating routine that is stored in memory 80 and capable of being carried out by the medical device. For example, in the illustrated embodiment, suppose that the internal access key "xxx" in the first memory location corresponds to the operating features of a CPAP device. Thus, in this example, the operating routine for causing the medical device to function as a CPAP device is stored in memory 80 and the access key "xxx" stored in the first memory location identifies the pressure support system as providing a CPAP mode of pressure support.

 Depending on the functional flexibility of the medical device and the...
- ...with the new set of operating features, is provided in the next available access key **memory** location. Suppose, for example, that the **CPAP** device is to be upgraded by changing the prescription pressure from its original value of...
- ...new internal access key, such as "yyy" is written into the next available access key memory location, as indicated by arrow 87. Suppose, for example, that the CPAP device is again upgraded by changing the CPAP device to a bi-level device. The operating routine is modified or completely rewritten to...
- ...bi-level operating features, such as "zzz" is written into the next available access key memory location, as indicated by arrow 89.

Each time the medical device is operated, controller 48 checks to determine whether a valid access key is stored in the access key memory locations. In this embodiment, if more than one access key is stored in this memory array, the controller will look for the access key that was the latest to be input to the medical device, for example, based on its position in the access key memory array. Checking to determine whether a valid access key is stored in memory involves generating an internal access key or retrieving an internal access key from a secure memory location and comparing the internal access key to the access key stored in the access key memory array. If these keys match, the medical device is thus capable of operating according to the operating routine stored in memory 80. If the keys to not match, or if there is no access key stored in the access key memory array, the medical device will not function, or will function at a reduced capability.

The present invention also contemplates that the access keys stored in the access key memory array effectively unlocks or enable additional or different operating features of the medical device, so that the particular location of the access key in the access key memory array is not important. In this embodiment, the present invention contemplates that the operating routine stored in memory 80 is capable of providing a number of different operating features. The particular operating features...

- ...determined based on what an access key or keys are stored in the access key memory array, which each access key unlocking a particular feature or set of features.

 In this...
- ...e., with the additional set of operating features, is provided in any available access key **memory** location. Suppose, for example, that the medical device is a bi-level pressure support device...
- ...new access key associated with this additional operating feature is added to the access key **memory** array, and the operating routine can be

modified or rewritten to cause the pressure support...

...feature only becomes enabled when the new access key is added to the access key memory array. Thus, the addition of access keys to the access key memory array effectively adds additional features to the medical device, either by unlocking existing operating features or by enabling additional programming to be stored in memory 90 that provides these additional features.

Again, each time the medical device is operated, controller 48 checks to determine whether a valid access key is stored in the access key memory locations. In this embodiment, the controller processes all of the access keys available for that medical device to find all of the valid access keys stored in this memory array. As with the previous embodiment, checking to determine whether a valid access key is stored in memory involves generating the internal access keys or retrieving the internal access keys from a secure memory location and comparing the internal access keys to the access key or keys stored in the access key memory array. If more than one valid access key is determined, the medical device is able...

...to not match, or if there is no access key stored in the access key memory array, the medical device will not function, or will function at a reduced capability.

Suppose...

- ...this operating feature). This requires adding an additional valid access key to the access key memory array that effective allows the medical device to provide this increase pressure level. If necessary, additional programming can be downloaded from the external device to the controller at that time to allow the medical device to provide this additional...
- ...manually controlled or adjusted as done conventionally. For example, the present invention contemplates that the IPAP and EPAP levels in the bi-level pressure support device in the above example can...
- ...features that are actuated or enabled by the access keys stored in the access key memory array are additive to one another. Meaning that each operating feature added to the medical...
- ...features that are actuated or enabled by the access keys stored in the access key **memory** array are cumulative but not necessarily additive. Meaning that each operating feature added to the...
- ...set of features that can be selected by the user.

For example, the access key memory array may be provided with two access keys, one key allows the pressure support device...embodiment of the present invention, the controller generates the appropriate internal access key for each memory location or for each operating feature that the medical device is capable of providing to...

...of the access key currently residing at that location or anywhere in the faccess key memory array. Generating the appropriate internal access key for each memory location or for each operating feature is accomplished by running an access key determination algorithm.

Preferably, this algorithm is permanently **stored** in the medical **device** is a non-erasable $memor\dot{y}$. The details of this algorithm should not be disclosed to the users of the medical...

- ...medical device are not generated using an algorithm, but are read from an non-erasable memory . Of course, appropriate security measures should be taken to ensure that these stored access key...
- ...seller or supplier who is interested in maintaining control over the upgrading of the medical **devices** .

With the **external** device and medical device configured to communicate with one another as shown, for example, in Fig...

...73, an exemplary embodiment of which is shown in Fig.4, is provided to the **external device**.

In a preferred embodiment of the present invention, the algorithm for performing the medical **device** upgrading process is **stored** on distribution **medium** 74, which is any information **storage medium** magnetic, **optical** or otherwise, such as tape, floppy disc, **memory** chip, CD-ROM, and DVD, that is capable of being physically delivered to the provider...

- ...process, for example, by running the upgrade program stored in a CD-ROM on their **computer** 34. The present invention also contemplates, however, providing the algorithm for performing the medical device...
- ...process using other conventional data transfer methods, such as downloading the upgrade software to the **external device** via a LAN, WAN, or internet communication link.

The medical device upgrading process is preferably presented to the provider, via **external device** 34, in the form of a wizard, which is step-by-step tutorial that prompts...

- ...step 88 and proceeds to an introduction step 90. In step 90, the user of external device 34 is presented with an introductory display. This display preferably appears on a display terminal 90 of external device 34 (Fig. 1) or on any other output device associated with the external device. The contents of the introductory display can include any desired material, such as a welcome...
- ...help option, one of several, further selectable help pages can be displayed.

In addition, any **computer** animation or other presentation techniques can be used to present information to the user.

In...

- ...upgrading" also includes reprogramming of the medical device that causes the device to have fewer operating features. For example, reprogramming an auto-titration device to function as a CPAP device, or eliminating certain features, such as an auto-on, auto-off capability, or compliance...

For example, the present invention contemplates that a medical device

manufacturer may supply a medical...triggering. Possible upgrades for such as device include adding a timed backup breath, adjusting the IPAP level, or both, reinstalling the operating routine, without making any functionality changes in...

...backup breath, and (2) whether to upgrade the bi-level software only, without adding or **deleting** any **operating** features. The **operating** routine for each type of upgrade is preferably stored in a single information **storage** medium 74.

It should be further noted that the present invention contemplates that upgraded operating routines...

- ...device, the upgrading process advances to communication link establishing step 94. In step 94, the **external device** and the controller in the medical device attempt to establish a communication link or to...
- ...been established. In an exemplary embodiment of the present invention, this is accomplished by causing processing unit 68 in the external device to select the appropriate communication protocol for the medical device and to provide a device available query to an available data port on the external device. The external device waits for a reply to the query from the medical device indicating that a valid communication link between the medical device and the external device has been established.

The present invention contemplates repeating this process for each available data port...

...link with the medical device, a communication error message and/or instructions for connecting the **external device** to the medical device can be displayed.

The present invention contemplates that once a valid communication link is established, the **external device** and medical device'will establish whether the medical device is a proper medical device for...

- ...to upgrade a bi-level device by adding a timed backup breath, but connects the **external device** to a **CPAP** device, it will not be capable of implementing the selected upgrade. In which case, a...
- ...all of the access key available to a medical device in a non-erasable, secure **memory** . In which case, step 104 involve retrieving the appropriate access key from the **memory** .

The present invention also contemplates that controller 48 compares the external access key with the...

...key. It is should be noted that this comparison step could take place in the external device. However, this would require that controller 48 download its internal access key generated in step 104 to the external device. In the interest of keeping the internal access keys secure, it is preferable that the internal access keys not be provided to the external device.

If the internal and external access keys do not match, controller 48 notifies the **external device** and an error message and/or other instructions provided to the user in access key...

...and external access keys match, the upgrading process takes place in upgrade step 108 and **memory** 80 is rewritten or modified with a new operating routine provided by **external device** 34 from distribution

medium 74.

During this process, the **external device** preferably displays a status bar indicating the status of the upgrading process, for example, the amount of data or time left in the data transfer operation involved in rewriting **memory** 80.

In step 108, the next available access key memory location is loaded with the access key, either internal or external, from step 102. In...

- ...key, either internal or external, from step 102 is provided to any available access key memory array location. It does not matter which access key, internal or external, is loaded, since they are identical. The access key is loaded in the access key memory array for the reasons discussed above. Namely, each time the medical device is operated, the...
- ...key generate by medic device in step 104, with the keys in the access key **memory** array. There must be a match before that device will operate with the set of...
- ...complete and the external access key has been rewritten into the last available access key memory location, the process ends in termination step 1 10. Preferably, an "upgrade complete" display is...
- ...above, in an exemplary embodiment of the present invention, the upgraded operating routine is preferably stored on a storage medium for easy delivery to the provider. The external access key and the storage medium containing the upgraded operating routine are delivered to the provider via any conventional delivery technique...medical device is accomplished by either modifying, in whole or in part, the operating routine stored in the medical device.

It is to be understood that the present invention contemplates other techniques for altering the...

...medical device. For example, several operating routines or sub-routines can be stored in the **memory** of the medical device. These routines or subroutines can be unlocked or locked by the...

Claim

... an internal access key is associated with each set of operating features of the medical device; providing an external device adapted to communicate with the controller;

establishing a communication link between the **external device** and the controller;

inputting an external access key to the **external device**; comparing the internal access key provided by the medical **device** with the

external access key; and
enabling upgrading of the medical device by enabling the operating
routine to...

...the enabling step,
upgrading the medical device by providing a second operating routine from
the external device to the controller, wherein the controller
thereafter executes the second operating routine causing the pressure...

- ...claim 1, wherein establishing the communication link includes providing a hard wired connection between the **external** device and the controller.
 - 7 The method of claim 1, wherein inputting the external access key to the external device includes manually entering the external access key into the external device via a keypad associated with the external device, or reading the external access key from a memory associated with the external device.
 - 8 The method of claim 1, further comprising downloading the external access key to the controller responsive to the internal access key being input to the **external device**, and wherein comparing the internal access key with the external access key takes place in...
- ...time the comparing step is to be performed, or (2) stored in advance in a **memory** in the medical device and recalled from the **memory** each time the comparing step is to be performed.
 - 10 The method of claim 1...
- ...the enabling step,
 upgrading the medical device by providing an upgraded operating routine
 from the external device to the controller, wherein the controller
 thereafter executes the upgraded operating routine causing the medical...
- ...of the medical device according to an operating routine executed by the controller and a **memory** associated with the controller that stores the operating routine, wherein a set of operating features...
- \ldots an internal access key is associated with each set of operating features of the

medical device; and

an **external device** (34) adapted to communicate with the controller via a

communication link between the **external device** and the controller, wherein the **external device** is adapted to receive an external access key, and wherein the controller or the **external device** compares the internal access key of the medical **device** with the **external** access key and enables upgrading of the medical device by enabling the operating routine to...

- ...claim 13, wherein the controller is adapted to receive a second operating routine from the **external device** responsive to the external access key matching the internal access key, and wherein the controller
- ...of claim 12, wherein the communication link is a hard wired connection (36) between the **external device** and the controller.
 - 17 The system of claim 12, wherein the $\ensuremath{\text{external}}$ device includes a keypad
 - (98) by which the external access key is manually entered into the external device .
 - 18 The system of claim 12, wherein the **external device** is adapted to download the external access key to the controller, and wherein comparing the...
- ...time an access key validation is required. @

- 20 The system of claim 12, wherein the **external device** upgrades the medical device by providing an upgraded operating routine from the **external device** to the controller responsive to an upgrade being enabled, and wherein the controller thereafter executes...
- ...of the medical device according to an operating routine executed by the processing means, and
 - memory means (80), associated with the processing means, for storing the operating routine, wherein a set...
- ...an internal access key is associated with each set of operating features of the medical device; and
 - an ${\tt external}$ device (34) adapted to communicate with the processing means
 - via a communication link between the **external device** and the processing means, wherein the **external device** includes means for receiving an external access key, wherein the processing means or the **external device** includes means for comparing the internal access key of the medical **device** with the **external** access key and for enabling upgrading of the medical device by enabling the operating routine...
- ...system (38) adapted to provide a flow of breathing gas to a patient under the **control** of the **processing** means, wherein the processing means executes a first operating routine stored in the **memory** to control the operation of the pressure generating system according to a first set of...
- ...23, wherein the processing means is adapted to receive a second operating routine from the **external device** responsive to the external access key matching the internal access key, and wherein the processing...
- ...of claim 22, wherein the communication link is a hard wired connection (36) between the **external device** and the processing means.
 - 27 The system of claim 22, wherein the external device includes a keypad
 - (98) by which the external access key is manually entered into the external device .
 - 28 The system of claim 22, wherein the **external device** is adapted to download the external access key to the processing means, and wherein comparing...
- ...time an access key validation is required.
 - 30 The system of claim 22, wherein the **external device** upgrades the medical device by providing an upgraded operating routine from the **external device** to the processing means responsive to an upgrade being enabled, wherein the processing means thereafter...
- ...available to the medical device supplier, that includes the first product identifier for the medical device and an external access key associated with both the medical device and an available upgrade; accessing the database...

- ...to be upgraded and the requested upgrade; providing the external access key to the medical device; comparing the external access key with an internal access key associated with the medical device; enabling an upgrade...device; and wherein providing the external access key to the medical device comprises: providing an external device adapted to communicate with the controller, establishing a communication link between the external device and the medical device, and inputting an external access key to the external device .
 - 38 The method of claim 37, further comprising, after the enabling step, upgrading the medical device by providing an upgraded operating routine from the **external device** to the controller, wherein the controller thereafter executes the upgraded operating routine causing the medical...
- ...method of claim 38, further comprising providing the upgraded set of operating features to the **external device** from the medical device supplier.
 - 40 The method of claim 38, wherein each internal access...
- ...the enabling step,
 upgrading the medical device by providing a second operating routine from
 the external device to the controller, wherein the controller
 thereafter executes the second operating routine causing the pressure...
- ...claim 37, wherein establishing a communication link includes providing a hard wired connection between the external device and the controller.

 46 The method of claim 37, wherein inputting an external access key to the external device includes manually entering the external access key into the external device via a keypad associated with the external device, or reading the external access key from a memory associated with the external device.

 The method of claim 37, wherein comparing the internal access key with the external access...
- ...to be performed, or (2) stored in advance in the medical device and recalled from **memory** each time the comparing step is to be performed.
 - 49 A method for a medical...
- ...available to the medical device supplier, that includes the first product identifier for the medical device and an external access key associated with both the medical device and an available upgrade; accessing the database...

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A SYSTEM FOR PROCESSING AND CUSTOMIZING VENTILATOR INFORMATION
SYSTEME DE TRAITEMENT ET DE PERSONNALISATION D'UNE INFORMATION DE
VENTILATEUR

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A SYSTEM FOR PROCESSING AND CUSTOMIZING VENTILATOR INFORMATION

Fulltext Availability: Detailed Description Claims

English Abstract

A network compatible **user interface** system is presented for displaying patient medical parameters and supporting user customization of medical parameter...

Detailed Description

A System for Processing and Customizing **Ventilator** Information This application claims the benefit of provisional U.S.

application, U.S. Serial No. 60/249,573 entitled "Ventilator Input" filed Nov. 17, 2000.

Field of tb e In ven tion This invention is...

...processing and displaying of medical information, and more particularly to processing, customizing and displaying of **ventilator** data in a network environment.

Ea ckgro un d of tb e In ven don...

... Such information may include

laboratory test results, care unit data, diagnosis and treatment procedures, and **ventilator** information associated with a given patient. **Ventilators** are commonly used to ventilate a patient's lungs with breathing gas, so as to...

...breathe on his or her own is somehow impaired. In order to properly administer the **ventilator**, a caregiver must first set up various settings for the **ventilator**.

Examples of commonly required settings to control a ventilator include: Peak Inspiratory Pressure (PIP) setting - limiting the peak τ

pressure during inspiration of air; and Positive End Expiratory Pressure (PEEP) setting - limiting the peak pressure at the end of expiration of air. Many other ventilator settings may also be controlled, depending on the capability of the particular ventilator .

In addition, some **ventilators** are equipped with various sensors so that a patient caregiver may monitor the condition of the patient through the **ventilator**. Examples of commonly monitored parameters for a **ventilator** include Mean Airway Pressure (MAP) - the mean pressure measured within the airway during the breathing...
...TVi)

measured volume of gas inhaled by the patient during a normal breath. Many other 'ventilator parameters may also be monitored, depending on the sophistication of the 'ventilator'.

The ability to set and adjust **ventilator** parameters and parameter settings, view default parameters, and customize these parameters and settings is of...

...is highly desired.

Summ ary of tb e In ven tion
A network compatible user interface system is presented for displaying patient medical parameters and supporting user customization of medical parameter...

...network source.

In another aspect, the system of the present invention comprises a network compatible user interface system for displaying patient medical parameters and supporting user customization of medical parameter image displays...

...shows an exemplary way of how customized parameters and settings associated with a patient and **ventilator** are displayed according to the present invention.

Detailed Description Figure I is an exemplary block...

...medical devices may be connected via
MIB 2; examples shown in Fig. 1 comprise a ventilator 6a, IV
(Intravenous) Pump 8 or other medical equipment 10.

MlB 2 is typically connected.:.connected directly to higher

level LAN 3. For example, as shown in Fig. 1, a $\,$ ventilator 6b and an anesthesia system 13 are connected directly to LAN 3, without the need...

...or other

types of private connection. Remote access gateway 19 may also be part of **server** 20, to be described below, instead of standing alone, as well know in the art.

According to the principles of the present invention, a central server 20 resides on LAN 3 for gathering and processing data from ventilators and other medical devices on network I for display and control. One skilled in the art can readily recognize that server 20 may reside at any level of the hierarchy of network 1, since all the...

\dots 4), as well as

remote sites in Fig. 1 are interconnected together. An example of server 20, is a ChartAssist server, marketed by Siemens Medical System. The server may be hosted, for example, by a computer system that is capable of running Microsoft NT operating system.

Medical data and lab results...

...acquired and correlated with a given patient for storage in relational data base 25 within **server** 20. Data base 25 may be of the type used for storing relational data such as the Microsoft SQL **server**.

In one aspect of the present invention, a user may use a Microsoft Windows compatible PC 26 or Windows NT compatible PC 27 as shown in Fig. 1, or any other computers capable of running a menu generating program such as a web browser program (e.g...

...with a given patient. That is, a user may use a web browser on any computer, as long as a communication connection can be made to server 20, to make request and view information acquired and stored in data base 25. This...

...course, a user

can simply use a keyboard and/or a mouse or any other user interface devices to enter a user selection or request on a user computer, as is known in the art.

Server 20 is therefore capable of formatting ventilator data to be compatible with, for example, HTML (HyperText Mark-up Language) programming language for displaying data on a web browser, The server is also responsive to, for example, HTTP (HyperText Transfer Protocol) commands originated from a user...

...Figs. 2A and 2B show in flow chart form, functions that may be performed by **server** 20 in accordance with the present invention. **Server** 20 first establishes communications with devices on the network as shown in step 202. This...

...higher

application-layer protocol, as well known in the art.

Once communications are established between server 20

and the other devices, **server** 20 starts to acquire parameters that are being monitored and settings selected for each ventilation unit (for example, 6a or 6b on network 1).

There are two different ways **ventilator** unit parameters and settings may be acquired by **server** 20 from each **ventilator** 6a or 8

b. In step 204, ventilator data are periodically acquired from each ventilator 6a or 6b automatically. The periodically acquired data are then stored in a database 25 within the server 20. In addition, step 206 shows that a "get ventilator" request may be received by server 20 from, for example, a user computer 26 to be described in more detail later. In this case, server 20 will instantly acquire new ventilation unit parameters and settings for the unit currently being viewed by user computer 26, without waiting for the current update period to expire, as shown at step 208. This "get ventilator" feature is particularly useful when critical, real time data are needed to make quick decisions...

... to wait for the next periodic update.

Fig. 4 shows an example of how the **ventilator** settings and parameters may be displayed on a web browser of a user **computer** 26, according to the present invention.

A user may request access to a particular **ventilator** by, for example, specifying the name of a particular patient or bed on the network (e.g., BER or 101 Bed 5) and by selecting on **ventilator** tab 301. An exemplary **ventilator** image chart display 400 is shown in Fig. 4 when the user selects chart icon 306. Exemplary image menu chart 300 displays, on the left most column, names of the **ventilator** unit parameters and settings 405 being displayed. The values of these parameters and settings are...

...time

when each value was sampled is specified in the upper row 415, A "get **ventilator** " function may be requested to obtain **ventilator** 9,

data. This function may be requested by user selecting "get ventilator" icon 417 in Fig. 4. In an exemplary embodiment, "get ventilator" icon 417 will only be active and capable of being selected on user computer 26 when the specified ventilator is recognized on hospital network I by server 20.

The displayed ventilator data are additionally processed by server 20 as described in Fig. 2B. As shown in step 210 of Fig. 213, once ventilator unit data are obtained from a particular ventilator unit such as ventilator 6a or 6b shown in Fig. 1, either instantly or periodically as described before, server 20 will prioritize the received ventilation unit parameters and settings for the particular ventilator. The server prioritizes the ventilator data in

response to user request and customization of data on a web browser on, for 'example, computer 26 to be described in more detail below.

In step 212, if data are obtained periodically, server 20 will compare newly acquired parameters and settings with existing or old parameters and settings...

...New data will

be stored in database 25 for display only if at least one **ventilator** setting or parameter has changed, as shown in steps 213 and 214.

This would allow...

...efficient use of database and bandwidth.

However, if data are obtained in response to "get ventilator" command, Server 20 will store the data, without doing any comparison to see whether data have changed...

...shown in steps 211 and 214.

10

In an exemplary embodiment, it is understood that **ventilator** parameters tend to change frequently (for example, M may changed for each inhalation by a patient), but on the other hand, **ventilator** settings tend to change infrequently. Therefore, it may be more informative and instructive for a...

...are displayed periodically (i.e., with changes highlighted) only if at least one of the **ventilator** settings, not parameters have changed. Therefore, in one alternative embodiment of the present invention, as shown in step 213, **ventilator** data will only be stored for display, if at least one **ventilator** setting has changed, regardless of whether any of the **ventilator** parameters has changed.

In step 215, server 20 will then allocate an attribute to distinguish newly acquired ventilation unit parameters and settings...

...and

parameters and settings. One exemplary attribute may be display color. That is, when the **ventilator** image chart shown in Fig. 4 is requested to be displayed via **computer** 26, **ventilator** data will be color coded on the web browser so that the user is able...

...time.

11

Referring now to Figure 3, there is provided an exemplary illustration of a **user interface** customization screen 300 displayable on a web browser of a user **computer** for integrating data acquired from multiple sources, including manual entry, into a single customizable display...

- ...first class comprising system parameter data, obtainable for example, via network sources such as the **ventilator** unit or monitoring **device** associated with a given patient at the bedside, and the second class comprising user-defined...
- ...3, access to the customization screen display 300 is accomplished via user selection of the **Ventilator** -> Create tabs (301, 305). User acceptance of the values entered on the screen stores the...
- ...retrieval of these values for display as a single column entry (e.g. 4101) in **ventilator** image chart display 400 (Figure 4).

An exemplary illustration of the network compatible user interface system for displaying patient medical parameters and supporting user customization of medical parameter image displays...

...previously mentioned, customization of data may be provided through a web browser on a user computer 12 in response to a user request via Ventilator -> Create tab selection for displaying customization screen 300. As shown therein, display 300 includes various ventilator parameters and settings for a selected ventilator associated with patient 3160.

Customization menu 3 00 incorporates a first window portion 3 1...and units of measure for later retrieval and display via both customization screen 300 and **ventilator** image chart display 400. This is advantageous, for example, for displaying certain parameters and settings of a ventilator or **ventilator** parameter that are not 13 recognized via the system but can be acquired at the bedside of a given **ventilator**.

Upon entry of custom parameters/settings, values, and units (332, 334, 336) and selection of...

...database 25
as default parameters that are then retrieved and displayed each time the Create **Ventilator** input screen tab (301, 305) is accessed.

In addition, web browser display generator software operates...

...user acceptance (340) by requesting and displaying the newly created/updated parameters or settings in **ventilator** image chart display 400, along with all other acquired **ventilator** parameters and settings from the network associated with the given patient.

Selection of the Set...

- ...current entry and update. These values may be edited and then saved as a new **ventilator** chart image entry on **ventilator** chart image display 400 (Figure 4). As previously mentioned, the Accept function 340 operates to...
- ...in window portions 310, 320 and 330 as a new chart 14 entry in the **ventilator** image chart display 400. More particularly, user entry and/or modification of data parameters/settings...
- ...control function results in a new column 4101 of parameter data generated and displayed in **ventilator** chart image display 400 corresponding to the manually entered values as well as any values maintained from the **ventilator** source. The selection of the **cancel** control **function** 380 **operates** to exit the customization screen 300 without saving the displayed data.

As shown in Figure 4, the ventilator chart image display 400 operates to display values of parameters identified by the user entered...

...the customization menu 300 (Figure 3) as well as from network sources such as the ventilator or monitoring device attached to the patient via the network. The ventilator chart image display 400 is activated in response to user selection of ventilator tab/icon 301 and chart sub tab 306. As previously mentioned, ventilator chart image display 400 is, also activated in response to selection of the accept control function 340 (Figure 3) which causes the system to obtain and display new ventilator data analagous to the "get ventilator " function previously described. Column 4101 (Figure 4) illustrates the results of such a selection, which includes manually updated setting values for PEEP set 3121 (value 10.7), MAP parameter

(value 22) and newly created AQ...

...new column 4101 all other settings and parameters (e.g. 3123) associated with the given ventilator unit 419 and patient 3160.

It is to be understood that the embodiments and variations...

Claim

- 1 A network compatible user interface system for displaying patient medical parameters and supporting user customization of medical parameter image displays...
- ...associated with said predefined listing of parameters and settings.
 - I 1. A network compatible user interface system for displaying patient medical parameters and supporting user customization of medical parameter image displays...
- ...claim 11, wherein said predefined list of parameters comprises parameters associated with one of (a) ventilation function and ventilation device settings and (b) blood gas characteristics.
 - 13 The system of claim 11, further including an...
- ...and acquiring a customization menu defined parameter from a network source. 19
 - . A network compatible user interface system for displaying patient medical parameters and supporting user customization of medical parameter image displays...

```
32/3,K/127
               (Item 127 from file: 349)
DIALOG(R) File 349: PCT FULLTEXT
(c) 2004 WIPO/Univentio. All rts. reserv.
00862015
            **Image available**
PORTABLE REMOTE PATIENT TELEMONITORING SYSTEM USING A MEMORY
                                                                   CARD OR
     SMART
             CARD
SYSTEME DE TELEMONITORAGE PORTATIF POUR PATIENT DISTANT UTILISANT UNE CARTE
    MEMOIRE OU UNE CARTE A PUCE
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PORTABLE REMOTE PATIENT TELEMONITORING SYSTEM USING A MEMORY
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     SMART
            CARD
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Detailed Description

Claims

English Abstract

...waveform ECG, full waveform respiration, skin temperature, and motion, and a connector which accepts a memory card or a smart for storage of the measured data. After a predetermined period of time, such as when the sensor band is removed , the memory card or smart card is removed and inserted into a monitoring device which reads the stored health parameter data of the subject. The monitoring device

includes a base station (30) that includes a **memory / smart card** reader and is connected to conventional phone lines (40) for transferring the collected data to...

Detailed Description PORTABLE REMOTE PATIENT TELEMONITORING SYSTEM USING A MEMORY CARD OR SMART CARD CROSS-REFERENCE TO RELATED APPLICATIONS The present application is a continuation-in-part application of...

- ...present invention is a low cost, patient-friendly, ambulatory monitoring system incorporating a low cost memory card or smart card for the remote electronic capture of noninvasive vital signs data including, e.g., full single...
- ...the monitoring equipment by electrical cords, thereby limiting the patienfs movement. In some prior art systems, the electrical cords have been removed and the transmissions to the monitoring equipment made using telemetry techniques; bowever, such systems have...
- ...the building wiring and the system is also designed to collect blood pressure, pulse rate, **respiratory** rate and the Hke and to relate that infori-nation to the physician via the...
- ...S.S. Ng describe yet another telemetry system. for ECG monitoring in an article entified `Microprocessor -based Telemetry System for ECG Monitoring, `IEEE/Ninth Annual Conference of the Engineering in Medicine ...
- ...therein describes a system for providing continuous ECG monitoring and analysis by means of a PC AT via wireless ...793; and 5,564,429 in which a patient wears a sensor harness including a microprocessor that detects potentially life-threatening events and automatically calls a central base station via radiotelemetry...
- ...and other costly components such as artificial intelligence software, sound and visual alarnis, and a microprocessor, As a result, the precordial strip patch is relatively expensive to manufacture and o erate ...
- ...unit includes a receiver, a processor for processing the received data to identify abnormalities, a **memory** for storing the sensed data, and circuitry for interfacing to a telephone line to send...
- ...only collected when the patient initiates the data download. Otherwlse, data is lost once the **memory** in the portable unit is full. No mechanism is provided for continuously collecting data, at...sensor device attached to the patient and stores the vital signs data on a mernory **card** or a **smart card** that may be inserted into the sensor device for data collection and/or transmits the...
- ...data logger or base station unit for processing and storage. In a first embodiment, a memory card is used that stores the vital signs data and is removed and its contents downloaded to a mornitoring device for performing processing and monitoring functions. In a second embodiment, the electronics of the disposable sensor device are provided on a removable smart card -typc device that may or may not have memory for storing the collected vital signs data. The electronics on the smart card may or may not include transmission circuitry for transmitting the vital signs data to a...

- ...sensor band with electrode patches, other sensors, and a connector dock for accepting a conventional memory card, such as an MMC memory card, for storing detected vital signs data, or a smart card that contains electronic circultry and may or may not contain memory. Additional intemal mernory equivalent or discrete memory may also be available on the memory card or smart card. The smart card preferably includes the sensor band's electronics so that the cost of the disposable sensor...
- ...time the sensor band may be discarded and replaced by a new sensor band. The memory card or smart card is ideally designed to store all vital signis data generated by the patient during that 24 hour period. The nieniory card or smart card is removed from the sensor band before the sensor band is discarded, and the memory card or sinart card is either mailed or carried to a rernote monitoring station or...
- ...to the rernote Monitoring station. Since the vital signs data is collected on a niemory card or smart card received in the sensor band, the patient is free to move around fteely while his or her vital signs are being moilitored. Once the data stored on the memory card or sniart card is uploaded, the memory card or smart card may be used again with another sensor band.

The second component is a base station having a **memory card** / **smart card**

reader for accepting the mernory- card or smart card, reading the vital signis data stored therein, and storing the vital signs data until the...

- ...and to process the stored data. For data transfer, the base station connects the mernory card or smart card, via modem and land or cellular telephone line, to the remote nionitoring station. Connections for...
- ...event fiags) forwarded by the sensor band and other sensors and simply requires a standard PC rurining, e.g., Windows NT. ECG analysis software and a user-friendly graplucal user interface are provided to remotely analyze the transmitted data and to perinit system maintenance and upkeep...
- ...subject. The sensor band in accordance with the invention includes a connector that accepts a memory card, such as a low cost MMC inemory card, that includes intemal memory for storing the health parameter data produced by the sensor band, or a specially designed smart that contains the signal processing circuitry (ADC, etc.) as well as any desiried memory . The memory card or smart card is then removed and inserted into a monitoring station including a inemory card/sniart card reader which is adapted to read the health parameter data from the card or smart card for display or farther processing. The memory mernory card or smart card may be taken or mailed to a remote monitoring station for data download, or, conversely, the memory card may be inserted into a base station, at the patietifs location for uploading the health parameter data from the memory card to the remote monitoring station via a ...in the or the **smart** database with the vital signs data from a plurality of other patients. A interface provides access to the vital signs data in the database for processing, medical diagnosis and/or analysis.

As noted above, the **smart card** also houses the sensor band's electronics so that the electronics may be reusable froin...

- ...next. Such electronics may include a rechargeable power supply that is recharged when the meniory card or smart card is inserted into the base station unit for data download. Altematively, the power supply may reside on the sensor band (e.g., in the smart card /niemory card connector) and be discarded with the disposable sensor band when the power supply is depleted...
- ...ECG, full waveform respiration, skin temperature, and motion and stores the measured data in the **memory card** or **smart card**. Auxiliary sensors are preferably provided at the base station, such auxillary sensors including, e.g, a blood pressure cuff, a spirometer, and weight scales. Also, the **user interface** at the remote monitoring station may contain full ECG analysis software covering waveform measurements, interval...
- ...of cardiovascular abnormalities includMig hypertension, congestive heart failure, arrhythmia, silent ischaernia, and the Eke, and respiratory abnormalities including chronic obstractive pulinonary disease, in a presently preferred implementation of the invention, the...
- ...I-lowever, those skilled in the art will appreciate that the use of a meniory card or such a smart card is not weIl-suited to real-time vital signs nionitoring unless the smart card includes transinission circuitry. Such transmission circuitry is included in another embodiment of the invention whereby...
- ...portable data loggeir or base station unit for remote storage. In such an embodiment, the **smart card** may or may not contain meniory for storing, the vital signs data and may or may not include the sensor electronies. Eowever, the inclusion of some **memory** on the **smart card** is preferred as it may act as a buffer in the event that the transmission...
- ...SPO21 skin temperature, and motion using the tecliniques of the invention.

FIGURE 3 illustrates the user interface to the base station unit provided in accordance with the invention.

FIGURE 4A illustrates a remote monitoring embodiment in which a **server** is used for data acquisition from a plurality of patients and the acquired data is...

...analysis.

FIGURE 4B illustrates a remote monitoring embodirment in which the end user has a **server** for data acquisition from. a plurality of patients, where the end user accesses the **server** directly.

FIGURE 5A illustrates a general block diagrami of the systema electronics in accordance with a first embodiment whereby a **memory** card stores the vital signs data.

FIGURE 5B illustrates a general block diagram of the system electronies in accordance with a second embodinient whereby a **smart card** stores the vital signs data and also includes the sensor electronics.

FIGURE 5C illustrates a general block diagram. of the system electronics in accordance with a third embodiment whereby the **smart card** includes reusable electronics for broadcasting the vital signs data to a personal

data logger where...

...general block diagram. of the system electronics in accordance with a fourth embodiment whereby the **smart** card includes the sensor electronies in addition to the reusable electronies for broadcasting the vital signs...

Claim

- ... measuring patient vital signs (health parameters) and storing the measured vital signs data in a **memory card / smart card** 20 and/or transmitting the measured vital signs data to a portlable data logger (not...
- ...connector port 13 disposed atop the signal processing circuitry 12 so as to accept the **memory** card/sinart card 20. As explained in more detail below, the sniart card differs from...
- ...in the connector and discarded with the used sensor band 1 0, or, alternatively, the **smart card** 20 may include rechargeable battery elements. The sensor band 1 0 is typically removed and...
- ...band 1 0 is randonily generated and sent in a repeating cycle f6r easy trackingofthevitalsignsdatastoredinthememorycard/ smartcard20.

 Thesensorband10 is designed such that the patient only has to prepare his or her skin...
- ...skin. in a position for measurement of the vital signs such as ECG. If a memory card or sniart card. 20 rather than intemal memory is used, the patient then inserts the memory card/sinart card 20 into the connector port 13 until (inverted exclamation mark)t engages...the sensor band 1 0 via a wired or wireless connection for storage on mernory card / smart card . 20. Signal processing circuitry 12 preferably includes a mierocontroller, such as an Atmel Atmega 103...
- ...signal), and then format the data stream into a predetermined format for storage in meinory/ smart card 20 or for transmission by a PIC microcontroller (not shown) to a transmitter of the smart card 20 at an appropriate data bit rate. During normal operation, digital data is obtained from a...
- ...leads of the ADC (corresponding to each of the ECG leads) every 4rnsec. Preferably, a **respiratory** measurement and a battery voltage measurement are also made via the ADC every 4 msec...
- ...Figures 5A-5D, the functionality of the microcontroller(s) will vary depending upon whether the **smart card** is equipped only for data storage (and. hence is a **memory** card) or is also equipped for data transmission. The microcontroller(s) of the signal processing...
- ...with respect to Figure 5, the signal processing circuitry 12 may be included in the **smart card** 20 so that the signal processing circuitry 12 may be reused from one sensor band...
- ...below). The signal processing circuitry
- 12 whether on the sensor band 10 or on the **smart card** 20, also may monitor the status of its circuitry and/or the battery level and...
- ...a low battery level. It should be noted thiat the ATmega 103 contains 4k of RAM for use as a stack, data buffers, and variable storage and 128k

of programmable flash...

- ...to store configurable parameters used by any software implemented by the processing circuitry of the **smart card** 20. As used herein, a 'meniory" card differs froril a "sinarf' card in that a **memory** card includes **memory** only, while a **smart card** also includes signal processing circuitry, such 16 as an A/D converter and transmission circuitry...
- ...and no data compression. In a currently preferred embodiment, data compression is used with a memory / smart card capable of holding at least 96 MB of compressed data so that selected data may be captured over a 24 hour period. Of course, larger or smaller memory devices may be used as desired in aecordance with cost and availability and the availability...
- ...enibodiment, a base station unit 30 can only receive vital signs data fr om a memory / smart card 20. Of course, memory /smart cards from a plurality of patients may be inserted into the base station unit 30 to be read, and the vital siglis data from each. memory / smart may be separately stored based on patient (inverted exclamation mark) dpntification infonnation stored on the memory / smart with the vital signs data. Hence, a single base station unit 30 may service...as a blood glucose meter could be connected to either connector 37 or 38. A memoryIsmart : card. reader 39 accepts memory / smart card 20 for reading the vital signs data stored thereon and, if rechargeable battery power is included on the memory / smart for recharging the battery power During operation, the base station unit 30 reads a inernory/ smart 20 or its equivalent inserted into the memory / smart card rea card reader 39 and stores all data received therefrom in ari internal memory . Preferably, the internal memory of the base station unit 30 is a hard disk **memory** , enabling storage of data until it is ready to be sent to the rernote i-nonitoring station 50. In a presently preferred embodiment, a memory having the capability of storing several days (eg@, 7 days) of data (at Icast 2 GB of memory at the sample rates descn'bcd herein and assuming no data compression) is desired. Preferably...
- ...spirometer, weight scales, and/or blood pressure) are stored separately and. aged independently in the memory of the base station unit 30 based on time stamps from. the sensor band 1 0 that may he stored on the memory / smart card . 20 to enable synchronization of the time stamps of the sensor band 10 and the base station unit 30. All data is retained in the base station memory until either (inverted exclamation mark)t is directed to be discarded by an instruction sent from the remote monitoring station 50, or until the base station memory is 18 full, at which point the carliest data is discarded first. In the preferred...
- ...monitoring station 50 via modem or, in an alternative embodirnent, locally using a laptop or PC . In the latter case, the base station unit 30 would have an interface for the optional connection of a PC or notebook computer for the 19 display of graphical data or for prograinming of the base station unit 30. The local PC or laptop could also be used for a simple video link with the remote monitoring...At the remote monitoring station 50, a physician or nurse has access to a normal PC connected by modem to the telephone line 40. Physiological monitoring software is run on this PC or on a networked system. to process the data received via the modem. fromthe base...
- ...or other electronic file for review by a physician. As illustrated in

- FIGURE 4A, a server 60 may be located in the transmission lines 40 to perinit data from a plurality of patients to be stored on the server 60 and provided to a plurality of remote monitoring stations 50 in a telemoniltoning center...
- ...used to simply monitor a single patient or several patients from a single remote monitoring PC running the server 52 and physiological monitoring software. At the start of any patient stady, the operator of ...
- ...operator will. be able to view the vital signs data most recently uploaded from the memory / smart card 20, even if such data is not otherwise scheduled to he downloaded by the base...as cardiac failure, hypertension, angina, ischacmia/coronary artery disease, peripheral vascular disease, acute and chronic respiratory insufficiency, history of recurrent arrhytlimias, sub-acute patients, post-infarction patients, acute and recurrent febrile...
- ...invention stores the vital signs data on a meniory/sinart card 20 inserted into a memory card connector dock 13 on the sensor band 1 0 and then reads the stored data froin the mernory/sinart card 20 using a memory / smart card reader 39 at a base station unit 30. Altematively, the smart card 20 includes transmission electronics for transinitting the vital signs data to the base station unit...
- ...Microcontroller 64 also provides the necessary supply and drive signals to the electrodes 62. A memory card connector dock 13 accepts the memory card 20 and includes a connector 13' which allows the conditioned vital signs data 66 from the microcontroller 64 to be stored on the niemory card 20. Memory card 20 thus receives data froni the microcontroller 64 including multiplexed sensor signal sample data. The sensoiband 10 continuously stores the data 66 including vital siglis data on the memory card 20, and the contents of memory card 20 are later given/mailed to the operator of the monitoring station 50 or inserted into memory card reader 3 9 of the base station unit 3 0 for later uploading to...
- ...from the ECG aud respiration signals, respectively. The received vital signs data is accumulated in **memory** 72 where it is stored until a remote monitoning station upload is initiated, at which...
- ...station 50 then processes and displays the received vital signs data using a conventional personal **computer** 78, as will be described in more detafl in the following section. In a preferred...data be compressed for faster data downloading to the remote monitoring station 50. Altematively, the **memory** card 20 may be mailed or returned to the remote monitoring station 50 for reading...
- ...nieniory/sinart card 20 may function as an on-body data logger preferably having enough **memory** to last 24 hours ((inverted exclamation mark).e., until the sensor band 1 0 is...
- ...be used with the next sensor band 1 0 while the contents, of the first memory /sinart card 20 are being downloaded. This embodiment simplifies the downstream electronies and removes the...
- ...freedom of movement is traded off against an increase in size and weight of the memory card 20 (approximately 2.5 tirnes the size of a wireless circuit at around. approximately...12 micluding microcontroller 64 and the associated battery/power components may be included en the smart card 20' as shown in Figure 5B. In this embodiment, the signal

- processing circuitry 12 as well. as the **memory** of the sinart: card 20'may be reused by respective sensor bands 1 0', thereby...
- ...bands 1 0'. As noted above, the. battery/power components need not be on the **smart** card 20',but may be included in the sensor band 1 T. This embodiment also has...
- ...embodiment illustrated in Figure 5C, the signal processing circuitry 12 may be included on the **smart card** 20" along with mierocontroller circuits and transmitter elements that transmit the vital signs'data over ...
- ...Though not shown, the base station unit 30 in this embodiment may also have a **memory** / **smart card** reader 39 as in the embodiments of Figures 5A and 5B. This embodiment allows for...
- ...circuitly including microcontroller 64 and the associated battery/power components may be included on the **smart card** 20... along with the signal transmission circultry as shown in Figure 5D. The embodiment of...
- ...of Figure 5C. As noted above, the battery/power components need not be on the **smart card** 20... but may be included in the sensor band 1 0'. In the embodiments of...
- ...way transmission for the acquisition of live data). These embodiments allow the electronics on the **smart** card 20" or 20... to be minimized to a much smaller weight and arca (approximately 12...
- ...Accordingly, it is currently contemplated that at least 96 Mbytes will be required for the **memory** card 20 or **smart** card 20' in the embodiments of Figures 5A and 5B or for the portable data logger...
- ...coulci allow for a much higher level of compression with a corresponding, cost saving in memory size. Als'o, the transmission circuitry of the smart card 20" or 20"' preferably inserts an identifier stored in an onboard EEPROM in order to...illustrates an embodiment of FIGURE 413 in which the remote monitoring station 50 includes a server 52 for managing the processing of the vital signs data received from the base station...
- ...fanctional arrangement would be utilized for implementing the embodiment of FIGURE 4A except that the **server** would be located in a separate physical unit or at a remote location. Each of...
- ...the base station-remote monitoring station communications protocol described in the previous section.
 - The main user interface 84 provides all normal user interaction with the
 - remote monitoring station 50. In the preferred embodiment, the user interface 84 has no custornization or set-up options; all such functionality is provided by the systema maintenance user interface 86. User interface 84 is designed to interface with the user manager 90, which maintains current state information...
- ...this is felt necessary (e.g. the schedule manager 82 may interface directly). Preferably, the user interface 84 embeds instances of the graphics control process 92 for controlling the display of graphical data.
 - The system maintenance user interface 86 provides control over any configurable parameters. In the preferred embodiment, an interface to the audit log 88 is provided from the system maintenance user interface

86 so that the operator may view the audit log. Preferably, settings that cause changes...

- ...that the user does not need to keep switching between the two modes. System maintenance user interface 86 also interfaces with the user manager 90, which maintains state infon-nation and the...
-state infonnation about a single Client user session. The coupling of user manager 90 to user interface 84 depends on the implementation methods actually used. Preferably, user manager 90 obtains auser name and password, from the user and then activates either the user interface 84 or the system maintenance user interface 86 depending on the privilege level of the user. User preferences and other settings are...a single phone line. Therefore, this aspect of the system will behave, independently from the user interface.

 Generally, download schedule manager 82 will use the case properties to download. data from the...
- ...monitoring station 50. In addition, it is preferred that any data download shall not cause data to be removed from the base station unit 30 such that the same or additional data could be...

...database 1 1 0. - 34

4 Security

For purposes of aecountability, and to simplify the user interface for normal users, it (inverted exclamation mark)S necessary to identify all users with a...

- ...audit record should. be kept in audit log 88 (FIGURE 6) separate from the patient database 1 10. Clearing the audit log 88 will only be possible by administrator level users. A checksum based...export/import; 35
 - 12 Data back-up/restoration/archiving; and
 - 13 Adding/removing users.
 - B. User Interface to Monitoring Software FIGURE 7 illustrates a diagram. of the top level uses of the...
- ...and shutting down/logging off the remote monitoring station
 - 50 The use cases and the user interface of the remoto monitoring station 50 used for implementing such use cases will be described...of the remote monitoring station softv@are will now be described with respect to the user interface screen displays of FIGURES 1 1 and 12. To use the remote monitoring station software...in patient compliance as compared to current telemetric monitoring methods. Though the use of a memory card 20 or sniart card 20' without transmission circuitry in accordance with the invention is not conducive to real-time monitoring, the use of a memoryIsmart card 20 is particularly well suited to non-real-time 44 monitoring as when monitoring...
- ...embodiment without materially departing from the novel teachings and advantages of the invention. For example, data processing such as ECG analysis coulu be perforned at the base station unit 30 and only...
- ...to the patient for use in downloading software and uploading data fromi/to an Intemet server for connection to a predotennined remote monitoring station connected to a designated node on the...
- ...were still required, connections could be built into the hardware of the

patient's, personal **computer** . All such modifications are intended to be included within the scope of this invention as...

...A health parameter data collection and nionitoring systein, comprising: at least one of a mernory card and a smart card which stores said health parameter data;

a sensor b and having a sensor assembly for...

...health parameter of the subject, said sensor band further comprising a connector which accepts said **memory card** or said **smart card** for storing said health parameter data produced by said sensor band; and

a monitoring station including a **memory / smart** card reader which (inverted exclamation mark)S adapted to read said health parameter data from said...niemory/sinart card reader and a nieniory which stores health parameter data read from said **memory** card or said sinart card until at least one of said health parameter data and...

 \dots energy to said sensor band. -47

14 A system as in claim 1, wherein said smart card is rechargeable.

15 A systein as mi claini 1 O, wherein said memory card or said smart card is adapted to store at least 24 hours' worth of said health parameter data.

16...

...band comprises signal processing circuitry that processes said health parameter data for storage on said memory card or said smart card.

17 A system as in claini 16, wherein said smart card further comprises FM signal transmission circuitry, said system further comprising a data logger in range...

...be downIoaded to sald monitoring station.

18 The system as in claim 1, wherein said **smart card** is adapted to receive health parameter data from at least a second sensing device.

19...

... subject motion.

20 A system as in claim 17, wherein at least one of said smart card and said data logger comprises data compression circuitry that compresses received health parameter data.

21...

...said FM signal transmission circuitry inserts an identifier that identifies at least one of said **smart card** and said sensor band as the source of the transrm'tted health parameter data.

22 A system as in claim 10, wherein said smart card comprises signal -48 processing circuitry that processes said health parameter data for storage on said mernory card or said smart card.

- 23 A system as in claim 22, whercin said **smart card** further comprises FM signal transmission circuitry, said system further comprising a data
- signal transmission circuitry, said system further comprising a data logger in range...
- ...monitoring station.
 - 24 A system as in claim 23, wherein at least one of said **smart** card and said data logger comprises data compression circuitry that compresses received health parameter data.

25...

- ...said FM signal transmission circuitry inserts an identifier that identifies at least one of said **smart card** and said sensor band as the source of the transmitted health parameter data.
 - 26 A health parameter data collection and monitoring systern, comprising: at least one of a **smart card** and a **memory** card which stores said health parameter data;
 - a sensor band having a sensor asseinbly for...
- ...health pararneter of the subject, said sonsor band further comprising a connector which accepts said memory card or said smart card for storing said health parameter data produced by said sensor band;
 - a base station unit including a **memory / smart card** reader aud a mernory which stores health parameter data read from said'mernory **card** or said **smart card**; and
 - a remote monitoring station connected to said base station unit via a communications link, said'rernote monitoring station uploading, via said communications link, health parameter data stored in said memory of said base station unit. -49
 - 27 A system as in claim 26, whercin said...said health parameter data and stores a summary of sald physiological parameter data in said **memory** for transmission to said remote monitoring station.
 - 28 A system as in claim 26, wherein said **memory** of said base station unit is a rolling first-in-first-out (FIFO) **memory** which stores said health parameter data irrespective of whether said health parameter data has been...
- ...input connection for accepting auxiliary data input from an auxiliary health parameter sensor and said **memory** stores said auxiliary data input for transmission to said remote monitoring station.
 - 30 A system...
- ...and ages independently said auxiliary data and said health parameter data while stored in said memory of said base station unit.
 - 32 A system as in claim 29, wherein said auxiliary...
- ...indicates ali event condition and stores event data indicating a significant physiological event in said **memory** when an abnormal physiological condition is detected.

 34 A systemi as in claim 33, wherein...

- ...and ages independently sald auxiliary data and said health parameter data while stored in said **memory** of said base station unit.
 - 35 A systein as in claim 29, whercin said base...
- ...said auxiliary data and stores a sunimary of said physiological auxiliary parameter data in said **memory** at said base station unit for transmission to said remote monitoring station.
 - 36 A system...
- ...performs ECG analysis of said health parameter data and stores ECG analysis data in said memory .
 - 37 A system as in claim 35, whercin said **memory** separately stores said health parameter data and said calculated physiological auxiliary parameter data.

38 A...

- ...35, wherein said remote monitoring station comprises a monitoring station processor and a monitoring station memory , said monitoring' station processor perfonning ECG analysis of said health parameter data and stores ECG analysis data in said monitoring station memory .
 - 39 A system as in claim 35, wherein said remote monitoring station comprises a mollitoring station processor and a monitoring station memory, said monitoring station processor perfonning respiratory rate analysis of said health parameter data and stores respiratory rate analysis data in said monitoring station mernory.
 - . A system as in claim 35, wherein said remote monitoring station comprises a monitoring station processor and a monitoring station $\tt memory$, sald monitoring station processor performing SpO, analysis of said health parameter data and stores SPO2 analysis data in said monitoring station $\tt memory$.
 - 41 A system as, in claim 29, wherein said remote monitoring station includes an interface...
- ...indicating an event condition and storing event data indicating a significant physiological event in said **memory** when said received health parameter data is outside said predeternuned ranges or when an abnormal physiological condition is detected.
 - 43 A system as in claim 42, wherein said **memory** of said base station unit is a rolling first-in-first-out (FIFO) **memory** which stores at least said health parameter data irrespective of whether said health parameter data...
- ...monitoring station.
 - 44 The system of claim 43, wherein said rolling first-in-first-out memory farther stores event data irrespective of whether said event data has been transmitted to said...units.
 - 54 A system as in claim 53, wherein said remote monitoring station includes a **server** which controls the reccipt and storage of health parameter data from said at least two...

- ...transmission to said portable data logger.
 - 58~A system as in claim 56, wherein said $\,$ smart $\,$ card . comprises signal processing circuitry that processes said health parameter data for transmission to said portable...
- ...of at least one health parameter of the subject; providing at least one of a memory card and a smart card for insertion into a connector of said sensor band, said memory card adapted to receive said health parameter data from said sensor assembly; and providing a monitoring station including a memoryIsmart card reader which is adapted to read said health parameter data from said memory card or said smart card for storage in a (inverted question mark) atabase.
 - 60 A method as in claim 59...
- ...of deten-nining whether the subject moved during a measurement of said health pa rameter data and deleting or ignoring health parameter data collected during a time the subject moved if such movement may have corrupted the...
- ...data indicative of values of at least one health parameter of the subject; providing a smart card for insertion into a connector of said sensor band, said smart card adapted to ...including a receiver which is adapted to receive said transmitted health parameter data from said smart card for storage in a database.
 - 72 A method as in claim 71, wherein said **smart card** comprises FM signal transmission circuitry, said method comprising the farther steps of providing a data...
- ...transmitting an identifier with said health parameter data that identifies at least one of said **smart card** and said sensor band as the source of the transmitted health parameter data.

75 A...

- ...that the drug/therapy has been provided and when; inserting at least: one of a memory card and a smart card into said sensor band, said memory card or said smart card storing said health parameter data and said event data; removing said memory card or said smart card after a predetermined period of time; and
 - inserting said **removed** mernory **card** or **smart card** into a remote monitoring station that captures said health parameter data and said event data...

32/3,K/132 (Item 132 from file: 349) DIALOG(R) File 349: PCT FULLTEXT (c) 2004 WIPO/Univentio. All rts. reserv. **Image available** FOR DETERMINING RESPIRATORY SYSTEM RESISTANCE METHOD AND **APPARATUS** DURING ASSISTED VENTILATION PROCEDE ET APPAREIL PERMETTANT DE DETERMINER LA RESISTANCE DU SYSTEME RESPIRATOIRE LORS D'UNE VENTILATION ASSISTEE Patent Applicant/Assignee: THE UNIVERSITY OF MANITOBA, 631 Drake Centre, Winnipeg, Manitoba R3T 5V4, CA, CA (Residence), CA (Nationality), (For all designated states except: US) Patent Applicant/Inventor: YOUNES Magdy, 321 Dromore Avenue, Winnipeg, Manitoba R3M 0J2, CA, CA (Residence), CA (Nationality), (Designated only for: US) Legal Representative: STEWART Michael I (agent), Sim & McBurney, 6th Floor, 330 University Avenue, Toronto, Ontario M5G 1R7, CA, Patent and Priority Information (Country, Number, Date): Patent: WO 200183014 A2-A3 20011108 (WO 0183014) Application: WO 2001CA578 20010425 (PCT/WO CA0100578) Priority Application: US 2000199824 20000426 Designated States: (Protection type is "patent" unless otherwise stated - for applications prior to 2004) AE AG AL AM AT AU AZ BA BB BG BR BY BZ CA CH CN CO CR CU CZ DE DK DM DZ EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX MZ NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG US UZ VN YU ZA ZW (EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR (OA) BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG (AP) GH GM KE LS MW MZ SD SL SZ TZ UG ZW (EA) AM AZ BY KG KZ MD RU TJ TM sel U.S.
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METHOD AND FOR DETERMINING APPARATUS RESPIRATORY SYSTEM RESISTANCE DURING ASSISTED VENTILATION

Main International Patent Class: A61M-016/00

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English Abstract

Method and apparatus are described for determining respiratory system resistance (R) in a patient receiving gas from a ventilator . A negative pulse in the pressure and/or flow output of the ventilator during selected inflation cycles is generated and Paw, V dot and V are measured at...

Detailed Description

TITLE OF INVENTION

METHOD AND APPARATUS FOR DETERMINING RESPIRATORY

SYSTEM RESISTANCE DURING ASSISTED VENTILATION

FIELD OF INVENTION

This invention relates to mechanical ventilation , and in particular, to assisted ventilation and the determination of respiratory system resistance.

BACKGROUND TO THE INVENTION

There are currently no reliable, clinically available, non-invasive means to estimate respiratory resistance (R) during inspiration in mechanically ventilated patients who have spontaneous respiratory efforts. Calculation of resistance requires knowledge of the force applied to the respiratory system which, in such patients, includes a component related to pressure generated by respiratory muscles (Pnius).

This component continuously changes during the inflation phase and cannot be estimated without prior knowledge of respiratory mechanics. Furthermore, to isolate 1 5 the component of total applied pressure that is dissipated against...

- ...P ...), it is necessary to subtract the pressure used against the elastic recoil of the **respiratory** system. This requires knowledge of passive **respiratory** elastance (E) which is also difficult to determine in the presence of unquantifiable Pinus. At...
- ...catheters, which add another invasive intervention to already much instrumented patients, or by elimination of respiratory muscle pressure output with paralysis, or hyperventilation (controlled mechanical ventilation, CMV). The latter entails additional personnel time and does not lend itself to frequent deten...
- ...prevailing R values, a feature that is of particular utility in pressure assisted modalities of **ventilatory** support (Pressure Support Ventilation, Proportional Assist Ventilation).

In US patent 5,884,622 (Younes), assigned...

...types of transient changes in flow in the course of the inflation phase of the **ventilator** .

The changes in airway pressure (Paw), flow (V), and volume (V) during these transient flow...

...of data points from each breath, greatly increases the computing and storage requirements of the **computer** used to process the information to provide the value of R. This requirement adds further strain on the extensive and highly complex operations carried out by modem, **computer** controlled **ventilators**.

SUMMARY OF INVENTION

The method and apparatus described in detail herein in accordance with the...

- ...in US patent 5,884,622. As indicated above, the main obstacle to deten-nining respiratory resistance during assisted ventilation is the uncertainty about what happens to Pinus during interventions in...
- ...that is clinically useful, such as in assisted ventilation
 In accordance with the present invention, respiratory resistance (R) is
 determined while allowing for the presence of pressure generated by
 respiratory muscles (Pmus) but without requiring knowledge of its actual
 value or an accurate I O value of passive respiratory elastance (E).

In accordance with one aspect of the present invention, there is provided a method of detennining respiratory system resistance (R) in a patient receiving gas from a ventilatory assist device (ventilator), comprising estimating the flow rate (V) and volume (V) of gas received by the patient from the ventilator, estimating pressure 5 near the airway

of the patient (Paw), generating a signal that results in a step decrease (negative pulse) in the pressure and/or flow output of the **ventilator** during selected inflation cycles, measuring Paw, 10 and V at a point (TO) near the...nining R.

In accordance with another aspect of the present invention, there is provided an apparatus which interfaces with ventilatory assist devices (ventilators) deterriuning respiratory system resistance (R), comprising a flowmeter, with associated electronic circuitry, that estimates the flow rate...

- ...from above mentioned circuitry and which is also connected to the control system of the **ventilator**, comprising.
 - circuitry that generates an output that results in a step decrease (negative pulse) in the pressure and/or flow output of the **ventilator** during selected inflation cycles;
- circuitry that measures Paw, V and V at a point (To... ...OF THE INVENTION
 - According to the equation of motion, the total pressure applied to the respiratory system (Pappi) is dissipated against elastic, resistive and inertial opposing forces. Thus.

Paw] @ Pe] + Pres...

- ...change in flow in I/see 2; V) and inertia (1). Because I of the respiratory system is very small (,zt@ 0.02 cmH20/1 /seC2), Pi,,r can be ignored...
- ...long as measurements are made at relatively low V (e.g. < IO I/seC2). In **mechanically ventilated** patients, V may exceed this level only in the first about I 00 1 5...

...Piner.

During assisted ventilation, Papp, is made up of two components, one provided by the **ventilator** (Paw) and one provided by the patient (Pmus). Thus, P_1 , P_2 = P_3 + P_4 Pmus. With this...

- ...Pmus and in volume can be ignored and APaw becomes APres. In practice, however, during **mechanical ventilation** it is not possible to instantly reduce flow from one value to another relatively stable At and A V /At are acceptably small). Even if flow exiting the **ventilator** is altered suddenly, a finite time must elapse before the flow to the patient stabilizes...
- ...of a known value of E, a default value, representing, for example, average E in **ventilator** dependent patients, can be used without much risk of significant errors. It should also be...
- ...one example will be illustrated which represents the most widely accepted behavior of R in mechanically ventilated intubated patients, namely that R is minimally (or not at all) affected by volume but default value (e.g. 28 cmH20/1, representing average E in mechanically ventilated patients (personal observations), may be used. Resistance can be obtained from the above equation (9...

...value.

Potential Sources of Errors and Approaches to Minimize such errors.

- 1) Measurement noise: In **mechanically ventilated** patients, the Paw and @7 signals are subject to noise from multiple sources. These include ...
- ...liquid in the tubing and oscillations or vibrations in the flow delivery system of the **ventilator** . The noise in the Paw signal may be in phase or out of phase with...
- ...flow, and vice versa. Also, such differences convert the relatively innocuous inphase oscillations originating from **ventilator** flow delivery systems to potentially more serious out-of-phase oscillations in Paw and flow...related to extrapolation of the Pmus trajectory.

These are potentially the most serious particularly when **respiratory** drive, and hence APmus/At, is high. The proposed approach involves the assumption that APmus...

- ...is easy to accomplish during Proportional Assist Ventilation (PAV). In this mode, the end of **ventilator** cycle is automatically synchronized with patient effort and is constrained to occur during the declining...
- ...Pmus . So long as pulses are not delivered in the last fraction (ca 30%) of **ventilator** TI, one is assured that Tj tennination did not occur within the pulse. With pressure...
- ...example, if a perturbation occurs regularly every 5 breaths, the patient may alter his/her **respiratory** output every fifth breath, even before the pulse is initiated. The occurrence of anticipatory responses...
- ...Pmus, independent of changes in electrical activation, through the operation of the intrinsic properties of respiratory muscles (force-length and force-velocity relations). An important contribution from either of these responses...my practical experience favors the extrapolation technique. Thus, it was found in studies on 67 ventilator dependent I 0 patients that the results of the extrapolation approach are in closer agreement...reflects the actual system used to validate the inventive procedures of the invention in 67 ventilator -dependent patients. The preferred embodiment has several components. Although in Figure 2, these components are...
- ...components, in actual practice all three components can be incorporated within a single unit (the **ventilator**).
 - A gas delivery unit I 0 is a **ventilator** system that is capable of delivering 0 proportional assist ventilation (PAV). A variety of mechanical...
- ...to the assignee hereof and the disclosure of which is incorprorated herein by reference. The **ventilator** illustrated in the preferred 5 embodiment consists of a piston 12 reciprocating within a chamber...
- ...A potentiometer 20 measures the piston displacement which corresponds to the volume change during the **ventilator** cycle. After certain corrections related to leaks and gas compression, this signal conveys the amount...
- ...controller 28 receives the flow and airway pressure signals. These can be obtained directly from **ventilator** outputs of flow (V) out and airway

- pressure (P). Alternatively, flow and airway pressure are...
- ...patient flow and airway pressure, reasonably accurate estimates can be obtained from sensors within the **ventilator** body, remote from the patient, after I 0 allowances are made for tube compression. The...
- ...clock circuit allows flow, pressure and volume to be sampled at precise intervals. The basic computer is an MC68HC16 with AM29FO10 ROM and KM68-1000 RAM. A preferred embodiment of the master computer program includes several functions as follows.
 - (1) A function to identify the beginning of inspiration...perturbations can be slowed down, as, for example, when the clinical condition is fairly stable. Clearly other methods of ensuring that pulses are applied at random intervals are possible.

Pulses may also be...

- ...sampled at about 6 insec or othre convenient time interval, to be stored in data **memory** over the entire period of inspiratory flow in breaths receiving pulses.
 - (5) A subprogram that...
- ...and volume at these four time points for each pulsed breath.
 - (7) A subprogram that **deletes data** points that fall outside the normal variability of the data. This subprogram also identifies breaths subjected to a pulse perturbation where certain criteria are not met. **Data** related to these observations are **deleted** from the tables.
 (8) A **program** that deten-nines the amplitude of pulses to be delivered. This is I 0 an...
- ...pulse is increased again. Conversely if the trough results in zero flow with resetting of **respiratory** cycle, the amplitude of the pulse is decreased. The intent of this subprogram is to...
- ...the negative pulses is close to, but not zero.
 - (9) A subprogram that causes early data to be deleted as new data are acquired, leaving only the results of a specified number of pulses (e.g. last 20 pulses) in the tables.
 - (10) A statistical subprogram to calculate the values of **respiratory** system resistance (R) from equations 8, 8a, 8 inter, 8a inter, 8 (bextra) and 8a...
- ...illustrated, the same functions performed by this micro controller can be incorporated into a resident **computer** within the **ventilator** by suitable programme.
- It is also recognized that the application of this technology is not...
 ...the specific piston-based PAV delivery system used in the above preferred embodiment. All commercial ventilators suitable for use in the Intensive Care Unit are capable of providing outputs related to...
- ...well within the skill of anyone experienced in the art. It is also evident that microprocessors and electronic accessories other than those described in the preferred embodiment can be utilized to... transient perturbations in pressure and flow are produced by

- a mechanical system independent of the **ventilator** itself and incorporated in the external tubing.
- 7) Where transient perturbations in pressure and flow...
- ...sake of determining resistance, are applied during modes other than PAV, including volume cycled assist, CPAP mode, pressure support ventilation or airway pressure release ventilation, whereby perturbations are produced by superimposing...
- ...TI.

SUMMARY OF DISCLOSURE

In summary of this disclosure, the present invention provides method and apparatus to determine respiratory resistance (R) during assisted ventilation of a patent in a unique and simplified manner. Modifications

Claim

- I . A method of determining $\ensuremath{\mathbf{respiratory}}$ system resistance (R) in a patient
- receiving gas from a ventilatory assist device (ventilator),
 comprising:
- estimating the Dow rate (V) and volume (V) of gas received by the patient from the $\ensuremath{\text{ventilator}}$;
- estimating pressure near the airway of the patient (Paw); generating a signal that results in a step decrease (negative pulse) in the pressure and/or flow output of the **ventilator** during selected inflation cycles;
- measuring Paw, V and V at a point (To) near the...
- ... nination of R.
 - 20 The method of any one of claims I to 19 including **deleting** early **data** as new **data** are acquired and reporting the results of the determination of R for a specified number...
- ...Paw or'@ is produced by an electromechanical system attached to the external tubing of the **ventilator** as opposed to directly interfacing with the **ventilator** control system.
 - 23 The method of any one of claims I to 22, wherein the...
- ...resistance values are used in closed loop control of an assist level provided by the **ventilator** .
 - 24 An apparatus which interfaces with ventilatory assist devices (ventilators)
 - determining respiratory system resistance (R), comprising: a flowmeter, with associated electronic circuitry, that estimates the flow rate is also connected to the control system of the ventilator, comprising:
 - circuitry that generates an output that results in a step decrease (negative pulse) in the pressure and/or flow output of the **ventilator** during selected inflation cycles;
 - circuitry that measures Paw, V and V at a point (To...

- ...by regression analysis performed
 on the results of two or more pulses applied in separate breaths .
 33 The apparatus of any one of claims 24 to 31 wherein a default elastance value (E) is...
- ...random intervals.
 - 39 The apparatus of any one of claims 24 to 38 including a user interface that permits the user to select one or more pulse characteristics.
 - 40 The apparatus of...
- ...aiialysis.
 - 43 The apparatus of any one of claims 24 fo 42 inchiding algorijbms which delete early data as new data are acquired, reporting the results of a specified number of Pulses. 44- The apparatus of...
- ...or V are produced by an electromechanical system attached to The external tubing of the **ventilator** as opposed to directly interfacing with the v=iilator control system.

 47 The apparatus of...

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               (Item 142 from file: 349)
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            **Image available**
APPARATUS FOR CONTROLLING A MEDICAL DEVICE
PROCEDE ET APPAREIL PERMETTANT DE SURVEILLER ET COMMANDER UN DISPOSITIF
    MEDICAL
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Fulltext Availability:
  Detailed Description
  Claims
English Abstract
  ...32, 32'), such as pressure support system, and a method of
  communicating with such a device using an information storage
   (34, 34'). The information storage device, in one embodiment, is
  adapted to be provided in a slot (70) in the medical...
```

...for controlling the operating of the pressure support device can be read

from the information **storage device**, information regarding the usage and/or operation of the pressure support device can be written to the information **storage device**, or both operations can be performed.

Detailed Description

- ... a medical device, and, in particular, to a medical device, such as a pressure support **system**, in which a **removeable** information **storage device** selectively inserts into a slot provided in the medical device for monitoring the use or...
- ...are well known. For example, it is known to use a continuous positive airway pressure (CPAP) device to supply a flow of breathing gas at a constant positive pressure to the...
- ...the flow of breathing gas effecting splints the airway, thereby preventing its collapse. Examples of CPAP devices are the REMstaro and Solo@ farnily of pressure support devices manufactured and distributed by Respironics, Inc. of Pittsburgh, PA.
 - In a typical CPAP device, the operating parameters, such as output pressure, and, hence, the flow of fluid delivered...
- ...level to be changed by an authorized caregiver or technician, so that a commonly designed CPAP device can be used to provide a pressure support therapy to patients requiring different pressure...
- ...as the needs of that patient change, without having to replace the patient's existing CPAP device with a new CPAP device. Of course, modifying the prescription level should only to be done under a careoriver...
- ...tightly controlled to prevent unauthorized tampering or inadvertent modification of the operating parameters of the CPAP device.
 - It is also known to provide a positive pressure therapy in which the pressure...
- ...breathing gas delivered to the patient varies with the patient's breathing cycle. A conventional **ventilator**, such as the Esprit@ **Ventilator**, also manufactured by Respironics, is an example of a pressure support or **ventilator** system in which the pressure of gas delivered to the patient varies between inspiration and...
- ...that delivers a flow of breathing gas to the airway of a patient, including a **ventilator** .

It is also known to vary the pressure delivered to the patient between inspiration and...

...pressure support.

With bi-level pressure support therapy, the patient's inspiratory positive airway pressure (IPAP) and expiratory positive airway pressure (EPAP) are each set to predetermined prescription levels so that the bi-level pressure support device provides the prescribed IPAP and EPAP pressures at the appropriate phase of the breathing cycle. Bi-level pressure support...

...to the patient based on whether or not the patient is snoring is the Virtuoso' CPAP family of devices manufactured and distributed by Respironics, Inc. This auto-titration pressure support mode...

- ...could occur and adjusts the pressure output to avoid this result is the Tranquility@ Auto CPAP device, also manufactured and distributed by Respironics, Inc. This auto-titration pressure support mode is ... pressure support device capable of operating in a PAV mode. Proportional positive airway pressure (PPAP) devices deliver breathing gas to the patient based on the flow generated by the patient. U.S. Patent...
- ... of operating in a PPAP mode.
 - Typically, the appropriate mode of pressure support, e.g., CPAP, bi-level, autotitration, PPAP, PAV, or a combination thereof is determined by the caregiver based...
- ...of the pressure support therapy. The operating parameters of the pressure support device, such as CPAP level, IPAP and EPAP levels in the case of a bi-level pressure support, percent of assistance...
- ...to the type of ided to the patient by the pressure support device, e.g., CPAP, pressure support treatment provi bi-level, auto-titration, PPAP, PAV, or a combination thereof. While...
- ...set up. For example, a typical bi-level pressure support system will operate as a CPAP device if the IPAP and EPAP levels are the same. Typically, once a patient is prescribed a mode of...
- ...that pressure support mode.
 - Those skilled in the art can also appreciate that a conventional ventilator system is typically capable of operating in different ventilation modes, with each mode representing a different technique for triggering and/or cycling the ventilator. It is common in a ventilator, for the caregiver to be able to select from a variety of modes of ventilation using selection devices provided on the ventilator. Because a ventilator is typically used in a hospital or other highly supervised environment, there is less chance...
- ...variables that can be altered or controlled in each operating mode. For example, in a CPAP device, the CPAP level is considered an operating parameter. In a bi-level device, the IPAP and EPAP levels are operating parameters. In the case of a PAV or PPAP device...for changing the mode or parameters using an authentication/authorization protocol, have access to the computer terminal on the device, or any combination thereof. As noted above, the pressure support device...
- ...the operating parameters of the pressure device have been set, the patient begins using the **device** to treat their **breathing** disorder and the operating mode and/or parameters remain in effect as long as the...
- ...example, it is not uncommon for an OSA sufferer to initially be treated with a CPAP device, and, thereafter, switched to a bi-level device in order to increase their comfort...
- ...requires that the patient receive an entirely new bi-level device in place of the CPAP device. This is obviously expensive and burdensome on the healthcare provider, who must deliver and install the new bi-level system in place of the existing CPAP device.

 Alternatively, a bi-level device could be prescribed to the patient with the IPAP and EPAP levels set to the same pressure for the CPAP treatment, then changed to different levels for the bi-level treatment.

However, this approach is also not practical because, as noted below, changing even the IPAP and/or EPAP prescription levels requires that the authorized person have access to the device...

- ...process and cannot be done by the patient. For example, if the patient's initial CPAP or IPAP prescription pressure is too low, increasing the prescription pressure requires that the pressure support device...
- ...or healthcare provider.

Most conventional pressure support systems generate compliance data and store it in **memory** for downloading to an external **computer** via an RS232 port and/or for display on a display screen in the pressure... ability to receive, identify and organize the incoming data, which requires a relatively complicated, automated **data processing** capability.

SUMMARY OF THE INVENTION

- Accordingly, it is an object of the present invention to... ...the exterior surface of the housing is sized and configured for selectively receiving an information storage device , which is small, light weight, and easily transported, for example, in the mail. A terminal associated with the slot enables the information storage device to communicate with the controller via the terminal when the inforination storage device is in the slot. This configuration enables the controller to read information from the information storage device , write information to the information storage device , or both when the information storage device is in the slot. In this manner, the information storage device can, for example, provide data to the controller for establishing the operating parameters of the...
- ...terminal are replaced with a transceiver operatively coupled to the controller, so that the information **storage device** communicates with the controller via the transceiver when the information **storage device** is proximate to the transceiver, thereby avoiding the need to physically place the information **storage device** in contact with the pressure support device. The controller reads information from the information **storage device**, writes information to the information **storage device**, or both via the transceiver.
- In a still further embodiment of the present invention, an...
 ...device is provided. The adapter, when provided in the slot in place of the information storage device, enables a variety of external devices, such as modem, a computer, or a communication device, to be operatively connected to the medical device, thereby enhancing the...
- ...of the pressure support system without adding dedicated communication links specific to each type of **external device** to be used.

It is yet another object of the present invention to provide an information storage device for use with a medical device, such as a pressure support system, to control its operation. In this embodiment of the present invention, the information storage device includes an identification storage area adapted to contain at least one of (a) information describing the information storage device itself, (b) information identifying a user to which the information storage device is assigned, and (c) information identifying a medical device assigned for use with the information storage device. The information storage device also includes an operating information storage area adapted to contain operating infori-nation for use...

- ...medical device.
 - It is yet another object of the present invention to provide an information storage device that receives and stores infori-nation from the medical device. In this embodiment of the present invention, the device includes an identification storage area information storage adapted to contain at least one of (a) information describing the infori-nation storage device itself, (b) information identifying a user to which the information storage device is assigned, and (c) information identifying a medical device assigned for use with the information storage device . The information storage includes a data storage area adapted to store data written thereon by the medical...
- ...regarding the use of the medical device, for example, can be stored on the information storage device. The information storage device is readily removeable from the medical device and can be provided to a monitoring center by simply mailing...
- ...a medical device having a slot defined in an exterior surface, (b) providing an information storage device that can be disposed in the slot, (c) inserting the information storage device into the slot, and (d) communicating information from the information storage device to the medical device or vice versa when the information storage device is in the slot. In this manner, the information storage device provides data to the controller for establishing the operating parameters ...DRAWINGS
 - Fig. I is a schematic diagram of a pressure support system including an information **storage device** according to the principles of the present invention; Fig. 2 is a front perspective view of a pressure support **device**, information **storage device**, and a remote monitoring/programming center according to the principles of the present invention;
 - Fig. 3 is a schematic diagram illustrating one embodiment of the storage areas ${}^{\prime}$
 - in the information **storage device** of Figs. I and 2; Fig. 4 is a schematic diagram illustrating various embodiments for the prescription data block in the information **storage device** of Fig. 3; Fig. 5 is a schematic diagram illustrating an alternative embodiment for the storage areas in the information **storage device** of the present invention; Fig. 6 is a schematic diagram of a further embodiment of...
- ...that generates a flow of breathing gas at an elevated pressure and an device 34 that communicates with a controller infori-nation storage 36 in pressure support device 32. As discussed in greater detail below, data, instructions, information, or commands from information storage device 34, in one embodiment of the present invention, are used to control the operation of the pressure support device. In addition, data or information from the pressure support device can be stored in the information storage device . Furthermore, the present invention contemplates that both of these functions can be performed so that information storage device 34 acts as a convenient and simple means for transferring information and/or instructions to or from the pressure support system. The details of information storage device 34 and its interaction with the pressure support device to achieve these functions are discussed...to the patient. For example, in a bi-level pressure support system, the change between IPAP to EPAP and EPAP to IPAP triggered based on the changes in the patient's breathing cycle, which is detected...

- ...support system. Still other external sensors can include EMG electrodes provided on the patient, a **respiratory** belt that measures movement of the chest and/or abdomen, and a motion sensor to...
- ...for use in providing between the user and the pressure support device. In addition, a **computer** or printer ten-ninal coupled to controller 36 can also constitute input/output device 60...
- ...controller 36, or both, can include a battery backup so that the operation of these **devices** or the information **stored** therein is not lost even if power to the pressure support device is interrupted.

As noted above, pressure support system 30 includes information storage device 34 that communicates with a controller 36. In an exemplary embodiment of the present invention, information storage device 34 is a so called " smart card " that contains a readable memory , a data storage area, or a combination of the two. Of course, information device 34 can also include an integrated circuit to provide card with additional independent processing capabilities, such as performing diagnostic routines on the pressure support device, analyze the data provided to the information storage device , increasing the processing capability of controller 36, or any other function capable of being performed by a processor. In a preferred embodiment of the present invention, information storage device 34 is approximately the size, weight and shape of a conventional credit card so that...

- ...or from the patient via U.S. mail or other conventional postal-type carriers.

 Information storage device 34 selectively inserts, as indicated by arrow A, into a slot 70 provided in housing...
- ...support device 32. A terminal 72 is provided within slot 70 so that the information storage device communicates with controller 36 when the information storage is properly disposed in the slot. As discussed below, controller 36 is capable of reading information from information storage device 34, writing information to the information storage device, or both. Terminal 72 is any conventional device capable of communicating with a smart card. As known to those skilled in the art, terminal 72 can include power couplings for providing power to the information storage device, where appropriate.

The present invention also contemplates that information storage device 34 is a conventional computer disc, such as a floppy disc, CDROM, or DVD storage device. In which case, terminal 72 includes the appropriate magnetic, electrical, or optical data accessing system for reading information from the disc, writing infon-nation to the storage device, or both.

One embodiment of the present invention contemplates that infon-nation storage device 34 provides the operating mode, operating parameters, or both for the pressure support system to controller 36. This embodiment enables the information storage device to be programmed at a remote location 74, such as at a pressure support monitoring...

...that can be provided by the patient's prescription CPAP, IPAP, EPAP, or maximum/minimum pressure can be stored on the information storage device at the remote location and mailed to the patient. The patient

merely inserts the information **storage device** into the slot in the pressure support system. Controller 36 reads the prescription pressure or

...breathing gas at the pressure level or within the pressure parameters specified on the information **storage device**. In a preferred embodiment of the present invention, the operating parameters read from the information **storage device** are **stored** in a **memory** (not shown) associated with controller 36 so that the information **storage device** can be **removed** and the pressure support device will continue to operate under the settings read from the information **storage device**, thereby eliminating the need for the information **storage device** once the pressure support device has been programmed.

It can be appreciated that this embodiment...

- ...purpose. Instead, the device provider or other caregiver merely sends the patient a new information **storage device** containing the new operating parameters. Alternatively, the patient can return the card to the device provider, who then **reprograms** the card at their **operating** center and returns it again to the patient. In either case, the burdens imposed on...
- ...the device provider has the ability to change the operating parameters stored on the information **storage device**, the security for the settings, i.e., operating parameters, of the pressure support device is
- ...pressure settings Fig. 3 is a detailed schematic diagram illustrating an exemplary embodiment of information storage device 34, and, in particular, the storage areas in the information storage device. Information storage device 34 in Fig. 3 is referred to as a "prescription card" because it contains information...
- ...pressure support device, and cannot receive data. In essence, it functions as a read-only **memory** card that sets the operating parameters of the pressure support device, which, in this embodiment...
- ...modifying, activating, or deactivating or otherwise controlling any other operating parameter using information or commands **stored** on information **storage device** 34.

In an exemplary embodiment of the present invention, information storage

device 34 includes the following three data storage areas: (1) a card identification block 76 that contains information describing the information storage device itself, (2) a user identification block 78 that contains information identifying a user to which information storage device 34 is assigned, and (3) a card prescription block 80 that contains contain prescription information...on their behalf. A card type block 84 contains information identifying the type of information storage device. As noted above, information storage device 34 is a "prescription card" in that it only contains information for setting the operating...

- ...pressure support device. The present invention, however, contemplates the existence of other types of information **storage devices**, such as a "data/prescription card" shown in Fig. 5 and described in detail below,
- ... to identify the specific format for the card identification block being

used in that information **storage device**. An address table block 88 in card identification block 76 defines the start and end...

...a unique card identification block that contains a card identification code unique to each information **storage device**, can be included in the card identification block.

This card identification code may be helpful in identifying and tracking the information **storage device**. In addition, the present invention does not necessarily require that each block 82-90 described...

...card identification block, so long as the card identification block contains information describing the information **storage** device to which the information **storage** device is assigned.

In the illustrated exemplary embodiment, user identification block 78 includes a user identification...

...to identify the specific format for the user identification block being used with that information **storage device**.

User identification block 78 also includes a user identification code block 94 and a user...

- ...94 contains at least one alphanumeric character that identifies a user to which the information **storage device** is assigned. For example, the user's social security number or a personal identification number (PIN) assigned by the card provider or the pressure support **device** provider may be **stored** in this block. User name block 96 contains information regarding a name of the user to which information **storage device** 34 is assigned. Preferably, the information contained in user identification code block 94, alone or...
- ...name information contained in user name block 96, uniquely identify a user to which information **storage device** is assigned.

The information contained in user identification block 78 can be used for security...

- ...a personalized greeting that is displayed on the input/output tenninal of the pressure support device when the information storage device is inserted into the slot in the pressure support device. This serves, for example, to notify the user that the information storage device has been correctly inserted into the slot and that he or she is using the correct information storage device. The present invention also contemplates that other information, such as information on the patient's medical condition, treatments, as well as advertisements can be stored on the information storage device and displayed to the user via input/output device 60. User identification block 78 includes...
- ...long as the user identification block contains information identifying the user to which the information **storage device** is assigned.

Card prescription block 80 includes a card prescription format block 102 that describes...to identify the specific format for the card prescription block being used in that information **storage device**.

Card prescription block 80 further includes an operating mode identification block 104 that identifies the...

...contain operating mode information identifying the mode of pressure

support to be provided as being CPAP, bi-level, auto-titration, PAV or PPAP, or a combination thereof. It should be noted...

- ...not be able to support certain modes of pressure support. For example, a relatively simple CPAP device is typically unable to provide bi-level, PPAP or PAV pressure support and cannot operate as an auto-titration pressure support system. If, for example, an information storage device in which operating mode identification block 104 specifies that the operating mode of pressure support is bi-level, is inserted into such a CPAP device, it may not be able to operate in this prescription mode. Therefore, an error...
- ...pressure support device or a bi-level device to be able to function as a CPAP device. The information contained in prescription identification block 104 would determine whether such a pressure support system would operate as a CPAP device or as a bi-level or an auto-titration device.

The present invention also...

...selected and altered, as needed, based on the operating mode information contained on the information **storage** device .

The present invention contemplates that when the information storage device is first produced, it is preferable that operating identification block 104 not specify any operating mode at all, so that the information storage device will only function as a prescription card after it has been appropriately programmed. For this...

...108 effectively locks or unlocks the ability to alter the pressure support system operating parameters **stored** in information **storage device** 34.

Ready for use block I IO contains information for controlling whether the prescription information can be read from the information **storage device**. For example, if controller 36 in Fig. I sees a zero flag in this block...

- ...information contained in card prescription block 80. This feature of the present invention enables information **storage device** 34 to function as a one-time, read only prescription device, so that once the prescription information is read from the information **storage device** by the controller, this prescription information cannot be read again. This is accomplished by having...
- ...to change to a zero after the prescription information is initially read from the information **storage device** by the pressure support device. One purpose of this feature of the present invention is to prevent unrestricted use of the information **storage device**.

Rather than have the controller not read the prescription information contained in card prescription block...

...card prescription block 80 in the first place.

The present invention also contemplates that information storage device 34 can be configured such that the information contained in ready for use block I...a zero flag in ready for use block I 10. This enables a single information storage device to be used to set of the operating parameters of multiple pressure support devices. If...

...or more secondary residences or temporary sleeping quarters, the patient need only carry the information **storage device** with them and use it to set up the same operating parameters on each device...

...purposes.

Fig. 4 illustrates various embodiments for the prescription information block 112 in the information **storage device** of Fig. 3. More specifically, prescription information block I 12a illustrates the prescription information for a **CPAP** prescription, prescription information block 112b illustrates the prescription information for an auto-titration prescription, and...

...the operating parameters for the pressure support device.

Prescription infon-nation block 112a for a CPAP prescription includes a CPAP pressure block II 6, which contains infon-nation defining the prescribed CPAP pressure.

Prescription information block 1 12a for a CPAP prescription also includes a ramp shape block I 1 8 and a ramp time block...

...and ramp shape blocks in prescription information block 112a or at other locations in information **storage device** 34 for specifying the duration and shape of ramps cycles initiated after the initial ramp...

...same pressure support therapy session.

In the illustrated embodiment, prescription information block 112a for a CPAP prescription includes an auto on data block 122 and an auto off data block 124...block 124.

Prescription infori-nation block I 12c for a bi-level prescription includes an IPAP pressure block 130 and an EPAP pressure block 132. IPAP pressure block 130 includes information defining the prescribed IPAP pressure, and EPAP pressure block 132 includes information defining the prescribed EPAP pressure. As with prescription information block II 2a for a CPAP prescription, prescription information block I 12c for a bi-level prescription includes ramp shape block...

...off data block 124.

As discussed in U.S. Patent No. 5,551,418, the $\ \ IPAP$, EPAP, or both can be controlled in a ramp fashion, 'ust as with the $\ \ CPAP$. Ramp shape block I 1 8' contains

information defining the shape for the change in the IPAP, EPAP or both during the ramp cycle. For example, the linear ramp selection in ramp shape block II 8' results in a linear increase in IPAP over the course of the ramp cycle with no change in the EPAP. The bi-level ramp selection results in a linear increase in both IPAP and EPAP during the ramp cycle. It can be appreciated that a great number of ramp shapes for IPAP and EPAP are possible, and information for selecting these ramp shapes can be provided in...

...operating parameters can be modified, controlled or set using the information contained in the information storage device .

For example, in a PAV or PPAP mode of pressure support, the degree or percentage...

- ...timed backup breath feature based on the information, instructions or commands contained in the information **storage device**. When enabled, the timed back-up breath feature causes the pressure support device, operating in...
- ...predetermined period of time. This is accomplished by providing a timer in the pressure support **device**. The **breathing** cycles of the patient are monitored in any conventional manner, and if the patient does...
- ...patient are examples of further operating parameters than can be input to the pressure support **device** via the information **storage device**. A still further embodiment of the present invention contemplates storing advertisements, a survey or questionnaire...
- ...or other information that may be relevant to the patient or caregiver on the information **storage device**. The advertisements, a survey or questionnaire, and/or other information are read from the information **storage device** and displayed on input/output device 60. If a question or a survey is provided...
- ...the answers to the survey and/or the scored results are stored on the information storage device for returning to the patient caregiver, either via the information storage device or via a communication link, such as the modem link discussed below. Presenting a questionnaire ...
- ...intended to require all of the abovedescribed operating parameters to be set by the information **storage device**. For example, there may be a situation where auto on or auto off is not...
- ...of the pressure support device can be set manually, i.e., without using the information **storage device**, or pre-set in advance, with the remaining parameters or operating mode being set by the data or commands contained on the inforination **storage device**.
 - Fig. 5 is a detailed schematic diagram illustrating another exemplary embodiment of an information **storage device** 34' for use in the pressure support system of the present invention. Information **storage device** 34' is similar to information **storage device** 34 of Fig. 3, except that information **storage device** 34' includes a data storage area 134.
 - Information **storage device** 34' in Fig. 5 is referred to as a "prescription/data card" because it contains...
- ...can also receive data, such as compliance data regarding the use of the pressure support device. Information storage device 34' includes the following data storage areas: (1) a card identification block 76' that contains information describing the information storage device itself, (2) a user identification block 78' that contains information identifying a user to which information storage device 34 is assigned, (3) a card prescription block 80 contains ...and (4) a card data control block 136.
 - In most respects, the features of information storage device 34' are identical to the those described above with respect to information storage device 34. For this reason, the common features of these two storage devices are not discussed below. However, the differences between these two types of information storage devices are

highlighted below.

Card identification block 76' includes a card type block 84' that contains information identifying the type of information storage device. As noted above, the type of information storage device 34' is a "prescription/data card", because it contains information for setting the operating parameters...

- ...138 that contains information identifying a pressure support system assigned for use with the information **storage device**. More specifically, pressure support device identification section 138 in the illustrated embodiment includes a unit...
- ...respectively, that together uniquely identifying a pressure support system assigned for use with the information **storage device**. This information can be used for security purposes to ensure that only the authorized prescription...
- ...containing information regarding the blocks of data stored in the data storage area.

Because information storage device 34' includes card prescription block 80, it can be used in the same manner as information storage device 34 to set the operating parameters of the pressure support system. However, the present invention contemplates omitting the card prescription block so that the information storage device cannot be used to set the operating parameters of the pressure support system, but can...

- ...support system, including information regarding the condition of the patient. In which case, the information **storage device** may be referred to as "data card", because its purpose is to store information provided...
- ...medical device. An example of "other information" that can be compiled by the infori-nation **storage device** includes data regarding the number of apneas experienced by the user the pressure support device...
- ...patient's pressure support therapy.

 Because of its small size and ease of use, information storage device 34' can be easily and inexpensively mailed to a monitoring center. The monitoring center can...
- ...therapy, for example. Because the monitoring center controls the input of data from the information **storage devices** they receive, the **data processing** requirements for compiling this data is minimized. As noted above, this information may be of...
- ...s caregiver to assess the patient's wellbeing.

In the embodiments described above, the information storage device is described as a smart card or other data storage medium that inserts into a slot provided in the exterior of the pressure support device. The present invention, however, contemplates other techniques for communicating between the pressure support device and the information storage device. For example, Fig. 6 illustrates a pressure support system 30' in which a socalled "contact-less" information storage device 152 communicates with pressure support device 32'. The pressure support system shown in Fig. 6 is identical to that shown in Fig. 1, except that instead of inserting the information storage device into a slot to communicate with controller 36, an antenna or other transceiver

154 is provided in place of the slot to communicate between controller 36 and information storage device 152 without the need for the device to physically contact the pressure support information storage device. This embodiment of the present invention enables controller 36 and the information storage device to communicate with one another merely by placing the information storage device in the vicinity of the pressure support system. The present invention contemplates that transceiver 154 can be any conventional device for transmitting data, information or commands to the infori-nation storage receiving data, information or commands, from the information storage device, or both. For example, transceiver 154 can be an RF, infrared, sonic, ultrasonic, or optical transmitter.

The present invention also contemplates that the transceiver can transmit energy to information **storage device** for powering any components of the information **storage device** that may require power. For example, it is known to use an electro-magnetic fieldthe present invention also contemplates providing a power source on the information **storage device**, such as a battery or solar cell, for powering the necessary components of the information **storage device**.

As noted above, the present invention contemplates providing slot 70 in the body or housing 66 of pressure support device 32 to enable the controller or processor 36 and the **smart** card infori-nation **storage device** 34 to communicate with one another via a terminal 72. The present invention contemplates utilizing...

- ...and terminal 72 for other purposes in addition to providing a docking port for information storage device 34. In particular, the present invention contemplates using slot 72 to communicate between an external device 160 and the components of pressure support device, such as controller 36. See Figs. 7...
- ...be provided in adapter 162. A communication link 172 selectively connects adapter 162 member to **external device** 160.

In the embodiment illustrated in Fig. 8, external device 160 is a modem 174 so that data, information, and/or instructions can be transmitted...

- ...part of the patient or caregiver, while still providing the flexibility to use an information **storage device** to control the pressure support device and/or monitor its operation.

 In a preferred embodiment...
- ...stored in modem 174, for example on a dedicated EEPROM device, as done in information storage device 34. This allows for a seamless transition between using the smart card information storage device 34 and modem 174 with adapter162, because the operating parameters of the modem can be initialized, loaded, and modified in the same manner done with the smart card information storage device.

In the embodiment shown in Fig. 8, modem 174 includes a first output device 178...

...174 to provide additional information to the user.

While a modem is contemplated as one **external device** that can be coupled to controller 36 in pressure support device 32 via slot 70, it can be appreciated that other **external devices** 160 can be coupled to

- controller 36 via slot 70. For example, a personal **computer**, palm or pocket **computer** or pocket organizer, printer, or any **computer** device can be coupled to the controller in pressure support device 32 by providing an...
- ...diagnostic routines on the pressure support device. Perhaps more importantly, the need for a dedicated **computer** tenninal, such as an RS-232 port is eliminated in favor of a multi-function port that can support both a **smart** card and an adapter.
 - A further embodiment of the present invention contemplates using adapter 162 to...70 in pressure support device 32, which normally only holds the credit card sized information **storage device**. As a result, it is necessary to ensure that the hardware remains engaged within slot...
- ...182, shown in Figs. 7 and 9, for maintaining a positive engagement between the information **storage device** and slot 70. In an exemplary embodiment of the present invention, retaining member 182 is...
- ...second members 188 adapted to receive internal interface portion 166 of adapter 162 or information **storage device** 34. Flexible arms 190 are provided on opposing sides of slot 184. The end of...
- ...a notch (not shown) provided on each side of internal interface portion 166 or information storage device 34, thereby increasing the resistance to pull out of the internal interface portion 166 or information storage device 34 from slot 70. In the embodiments discussed above, the information storage described for use in conjunction with a pressure support system. It is to be understood, however, that the present invention further contemplates using the infori-nation storage device as a means to communicate with and/or control the operation of other medical devices . For example, information storage device can be provided in a glucose monitor so that each time the patient checks his or her blood sugar level, the results are stored on the information storage device , which can then be sent to the caregiver for review or analysis. Other medical devices in which the above-described information storage device technique for communication can be used include: light therapy devices, magnetic therapy devices, pulse oximeters...

Claim

- ... of the housing, wherein the slot is sized and configured for selectively receiving an information **storage device**, and a terminal (72) associated with the slot such that an information **storage device** communicates with the controller via the terminal responsive to the information **storage device** being disposed in the slot, wherein the controller is adapted to at least one of (1) read information from the information **storage device** and (2) write information to the information **storage device** via the terminal.
 - 2 The pressure support system of claim 1, further comprising at least...
- \dots coupled to the controller for monitoring usage of the pressure support system.
 - 6 An information storage device (34) adapted for use with a medical device,
 - the information storage device comprising:
 - an identification **storage** area (76, 78) adapted to contain at least one of (1) information describing the information **storage** device itself,
 - (2) information identifying a user to which the information storage

device is assigned, and (3) information identifying a medical
device assigned for use with the information storage device; and
a first information storage area (80) adapted to contain operating
information for use in controlling an operation of such a medical device

7 The information storage device of claim 6, wherein the identification storage area includes both 1) an information storage device identification area (76) adapted to contain information describing the information storage device itself and 2) a user identification area (78) adapted to contain information identifying a user to which the information storage device is assigned.

- 8 The information **storage device** of claim 7, wherein the identification area further includes a medical device identification area adapted to contain information uniquely identifying a medical device assigned for use with the information **storage device**.
- 9 The information **storage device** of claim 8, further comprising a data storage area adapted to store data written thereon by such a medical
- 10 The information **storage device** of claim 6, further comprising a data

storage area adapted to store data written thereon by such a medical device. 1 1. The information **storage device** of claim 6, wherein the first information

storage area includes:

device .

- a patient name area adapted to contain information regarding a name of a user $% \left(1\right) =\left(1\right) +\left(1$
- to which the information **storage device** is assigned; and a patient identification area adapted to contain at least one alphanumeric character identifying a user to which the information **storage device** is assigned.
- 12 The information **storage device** of claim 6, further comprising a first control data storage area adapted to contain information that controls whether the operating information can be read from the information **storage device**.
- 13 The information **storage device** of claim 6, further comprising a second control data storage area adapted to contain infon-nation that controls whether the **operating** information can be **erased** from the information **storage device**.
- 14 The information **storage device** of claim 6, further comprising a display data storage area adapted to contain information to be displayed on such a medical **device**.
- 15 The information **storage device** of claim 6, wherein the medical device is a pressure support device, and wherein the...
- ...pressure support device and operating parameter information designating an operating parameter of the pressure support device .
 - 16 An information **storage device** adapted for use with a medical **device**, the

information storage device comprising: an identification storage area adapted to contain at least one of (1) information describing the information storage device itself, (2) information identifying a user to which the information storage device is assigned, and (3) information identifying a medical system assigned for use with the information storage device; and a data storage area adapted to store data written thereon by such a medical device.

- 17 The information storage device of claim 16, wherein the identification storage area includes both a storage device identification area adapted to contain information describing the information storage device itself and a user identification area adapted to contain information identifying a user to which the information storage device is assigned.

 The information storage device of claim 17, wherein the
- identification area further includes a medical device identification area adap

area further includes a medical device identification area adapted to contain information uniquely identifying a medical device assigned for use with the information storage device.

- 19 A pressure support system (30, 30') comprising: a pressure support device (32, 32') comprising...
- ...surface of the housing, and a terminal (72) associated with the slot; and an information storage device (34) adapted to be selectively disposed in the slot, the information storage device comprising: an identification storage area (76, 78) adapted to contain information identifying at least one of (1) information describing the information storage device itself, (2) information identifying a user to which the information storage device is assigned, and (3) information identifying the pressure support device assigned for use with the information storage device, and at least one of (a) a first information storage area (80) adapted to contain...
- ...data written thereon by the pressure support device, wherein the controller communicates with the information storage device via the terminal responsive to the information storage device being disposed in the slot, and wherein the controller is adapted to at least one of (1) read information from the information storage device and (2) write information to the information storage device via the terminal.
 - 20 The pressure support system of claim 19, further comprising an adapter \dots
- ...disposed in the slot, wherein the adapter provides communication access between the controller and an **external device** responsive to being inserted into the slot.
 - 21 The pressure support system of claim 19...
- ...a medical device having a slot defined in an exterior surface thereof; providing an information storage device sized and configured to be selectively disposed in the slot; inserting the information storage device into the slot; and

communicating information from the information **storage device** to the medical device responsive to the information **storage device** being disposed in the slot.

- 24 The method of claim 23, further comprising causing the medical device to operate in a predetermined manner based on information read from the information storage device responsive to the information storage device being inserted into the slot.
- 25 The method of claim 24, further comprising preventing such a medical device from receiving the information from the infori-nation **storage device** after the inforination has been initially provided to such a medical device.
- 26 The method:..
- ...comprising:

monitoring usage of the medical device; and writing information regarding usage of the medical device onto the information storage device.

- . The method of claim 23, further comprising prompting a user to **remove** the information **storage device** responsive to an occurrence of a predetermined condition.
- 28 The method of claim 27, wherein the predetermined condition includes: a failure of the medical device to communicate with the information storage

device ,

an elapse of a predeterinined amount of time since the information ${\bf storage}$

device was disposed in the slot in the pressure support device, and an accumulation of data in the information **storage device** exceeding a predetermined threshold.

- 29 The method of claim 23, further comprising writing information from the pressure support device to the information storage device.
- 30 The method of claim 29, further comprising: removing the information **storage device** from the slot in medical **device**;

transporting the inforination **storage** device to a remote location; and

downloading information concerning the pressure support **device** from the information **storage device** at the remote location. 3 1. A method of reporting information from a medical device...

...e support device having a slot defined in an exterior surface thereof;

providing an information **storage device** sized and configured to be selectively

disposed into the slot;

inserting the infon-nation **storage device** into the slot; and communicating information to the information **storage device** from the medical device responsive to the information **storage device** being disposed in the slot.

32 The method of claim 3 1, further comprising:

removing the information **storage device** from the slot in medical **device**;

transporting the information **storage** device to a monitoring center; and

downloading information concerning the pressure support device from the

information storage device at the monitoring center.

- 33 The method of claim 3 1, further comprising: monitoring usage of the medical device; and writing information regarding usage of the medical device onto the information storage device.
- 34 The method of claim 3 1, further comprising prompting a user to remove the information storage device responsive to an occurrence of a predeten-nined condition.
- 35 The method of claim 34...
- ...the predetermined condition includes:
 - a failure of the medical device to communicate with the information $\ensuremath{\mathbf{storage}}$

device ,

an elapse of a predeten-nined amount of time since the information storage

device was disposed in the slot in the medical device, and
an accumulation of data in the infon-nation storage device exceeding
a
predetermined threshold.

36 A pressure support system (30, 30') comprising: pressure generating means...predetermined condition includes:

a failure of the pressure support device to communicate with the information

storage device,

an elapse of a predetermined amount of time since the information ${\bf storage}$

device was disposed in the slot in the pressure support device, and an accumulation of data in the information **storage** device exceeding a predetermined threshold.

- 39 The pressure support system of claim 36, further comprising monitoring
- ...further comprising means for preventing the controlling means from receiving operating inforination from the information storage device after such operating information has been initially provided to the pressure support device.
 - 42 The...
- ...within the receiving means, for providing a communication link between the controlling means and an **external device** responsive to being disposed on the receiving means.
 - . A pressure support system (30, 30') comprising...
- ...pressure generating system;
 - a transceiver (154) operatively coupled to the controller such that an information storage device (152) communicates with the controller via the transceiver responsive to the information storage device being disposed proximate to the transceiver, wherein the controller is adapted to at least one of (1) read information from the information storage device and (2) write information to the information storage device via the transceiver.
 - 44 A method of configuring and pressure support system, comprising:

providing a pressure support system having a slot defined in an exterior surface thereof; providing an information storage device sized and configured to be selectively disposed in the slot; inserting the information storage device into the slot; communicating first information from the information storage device to the medical device responsive to the information storage device being disposed in the slot; and configuring the pressure support system based on the first...

...further comprising preventing the pressure support system from receiving the first information from the information storage device after the first information has been initially provided to such a medical device.

47 The...

...support system; and writing information regarding usage of the pressure support system onto the information **storage device**.

32/3,K/153 (Item 153 from file: 349) DIALOG(R) File 349: PCT FULLTEXT (c) 2004 WIPO/Univentio. All rts. reserv. **Image available** METHOD AND APPARATUS FOR OBTAINING PATIENT RESPIRATORY DATA PROCEDE ET APPAREIL D'OBTENTION DE DONNEES RESPIRATOIRES D'UN PATIENT Patent Applicant/Assignee: MEDTRAC TECHNOLOGIES INC, Suite 210, 6950 W. Jefferson Avenue, Lakewood, CO 80235, US, US (Residence), US (Nationality) MCKINNON Robert J, 10036 S. Stratford Pl., Highlands Ranch, CO 80124, US RILEY Patrick L, 1204 E. Crandall Avenue, Salt Lake City, UT 84106, US WOLF James L, P.O. Box 1002, Conifer, CO 80433, US Legal Representative: ZINGER David F, Sheridan Ross P.C., Suite 1200, 1560 Broadway, Denver, CO 80202-5141, US Patent and Priority Information (Country, Number, Date): (US) 6190 326 Patent: WO 200064346 A1 20001102 (WO 0064346) Application: WO 2000US10550 20000420 (PCT/WO US0010550) Priority Application: US 99299195 19990423 Designated States: (Protection type is "patent" unless otherwise stated - for applications prior to 2004) AE AL AM AT AU AZ BA BB BG BR BY CA CH CN CR CU CZ DE DK DM EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MA MD MG MK MN MW MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT TZ UA UG UZ VN YU ZA ZW (EP) AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE (OA) BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG (AP) GH GM KE LS MW SD SL SZ TZ UG ZW (EA) AM AZ BY KG KZ MD RU TJ TM Publication Language: English Filing Language: English Fulltext Word Count: 11430 METHOD AND APPARATUS FOR OBTAINING PATIENT RESPIRATORY DATA Main International Patent Class: A61B-005/08 Fulltext Availability: Detailed Description Claims English Abstract A system for collecting patient respiratory information includes a base unit (12), and a removable mouthpiece unit (14). The mouthpiece unit (14) includes sensors that sense parameters of a patient's breath... ...in chronological fashion for later analysis by a physician. The mouthpiece unit (14) includes a memory for storing identification information for a patient who has been assigned the mouthpiece unit (14

Detailed Description

METHOD AND APPARATUS FOR OBTANING

PATIENT RESPIRATORY DATA

FIELD OF TBE INVENTION

The invention relates generally to medical devices and, more specifically, to devices for measuring and logging patient respiratory information.

BACKGROUND OF THE RWENTION

Respiratory problems are relatively common in society today. For example, some I 0 estimate that nearly 5% of the population of the United States suffer from asthma.

Effective treatment of **respiratory** conditions can be complicated, sometimes requiring continuous monitoring and recording ofrespiratory function and symptoms in...

...threatening attacks or the like.

As can be appreciated, the procedures for monitoring and recording respiratory function and the use of medicines can be complicated and time consuming. Much of the responsibility for maintaining accurate records of respiratory function and administration of medication falls upon the patient, who must then report recorded information...

- ...need exists for a method and apparatus for accurately collecting information about a patient's respiratory condition from the patient.The method and apparatus will preferably be simple and straightforward to ...
- ...present invention relates to a system that is capable of accurately collecting and recording patient respiratory information for use, for example, in developing/modifying a treatment regimen for the patient. The system includes both measurement functionality for measuring the patient's present respiratory condition and storage functionality for storing and organizing the measured information. In addition, the system...
- ...patient management functionality can prompt the patient when it is time to take an appropriate **respiratory** reading and also coach the patient during the reading to increase the likelihood of proper...
- ...conjunction with input/actions by the patient. In addition, the system includes at least one **detachable** mouthpiece **unit** for insertion into the base unit when a measurement is to be performed. The mouthpiece unit includes the sensors that are required for sensing **respiratory** function related parameters from a patient's breath when the patient blows, or possibly inhales...
- ...with any relevant treatment suggestions.

In accordance with one aspect of the present invention, each **detachable** mouthpiece **unit** includes an internal **memory** for storing, among other things, identification information identifying a patient having exclusive use of that...

- ...unit is transferred to the base unit which stores the identification information in its internal **memory**. Results ofall subsequent tests performed by the base unit using that inserted mouthpiece unit are...
- ...unit, can make use ofa single base unit without confusion I 0 as to which respiratory -related information corresponds to which patient. In addition, because each patient uses an entirely different...one embodiment of the present invention. As illustrated, the system 10 includes: a portable base unit 12, a detachable mouthpiece unit or device 14 which can be removably coupled to the portable base unit 12, a

- ...unit 12 includes the measurement and storage functionality that is used to collect and record **respiratory** related information for the patient. The mouthpiece unit 14 plugs into the base unit 12...
- ...base unit 12 can be carried by a patient for use in collecting and storing respiratory -related information about the patient as the patient goes about his ordinary daily routine. Alternatively...
- ...a multiple patient environment, such as a hospital or a home having two or more **respiratory** patients, to collect data from a number of different patients. As win be described in...
- ...patient (e.g., whether the patient inhaled the medication too fast, etc.). As with the **respiratory** measurement information, this information is also stored within the base unit 12 for future use...
- ...in the base unit 12 for the identified patient and stores it within an internal memory. The stored data is then transferred to the physician data collection station 18 via communication path 20 at an appropriate time.

After the **respiratory** -related data has been transferred to the docking station 16, it does not have to...

- ...data collection station 18 is a device used by a physician to retrieve and organize respiratory information about his patients. Typically, the physician data collection station 18 will be a desk top personal computer used by the physician to perform and organize his daily practice. After a patient's respiratory -related information has been transferred to the physician data collection station 18, the physician analyzes...
- ...docking station 16, via the communication path 20, where it is stored in the internal **memory** of the docking station 16. If the corresponding base unit 12 is still docked within...
- ...by the patient. Otherwise, the docking station 16 will hold the information in its internal **memory** until the appropriate base unit 12 is re-inserted. Alternatively, the physician can call the...
- ...device can be used within the base unit 12, including, for example, a general purpose microprocessor, a digital signal processor, a reduced instruction set computer, or a complex instruction set computer. Because the portable base unit 12 is battery powered, processors capable of low power operation...
- ...12 includes: a measurement unit 38, a patient performance manager (PPM) 40, a performance event **memory** 42, a wireless transceiver 44 coupled to a transducer 45, a voice synthesis unit 46...
- ...the LCD display 50 or the speaker 54 when it is time to take a respiratory reading. Likewise, the PPM 40 can query the patient with respect to any symptoms the...

...time.

The PPM 40 then records the patient's activities/responses in the performance event **memory** 42 in a chronological fashion. In one embodiment, all entries stored in the performance event **memory** 42 are time tagged with both date and time-of-day so that an accurate time

record is maintained of the patient's activities.

When a **respiratory** measurement is to be performed, the PPM 40 first checks to determine whether a **detachable** mouthpiece **unit** 14 is currently installed. If not, the patient is prompted using the speaker 54 and...

- ...installed, it enables the measurement unit 38 to receive and process raw data from the **detachable** mouthpiece **unit** 14. The PPM 40 then prompts the patient to blow into the mouthpiece unit 14...
- ...unit 38, the PPM 40 stores the results of the processing in the performance event **memory** 42 as described above. The PPM 40 can also display the results of the processing...
- ...one aspect of the present invention, the mouthpiece 1 5 unit 14 includes an internal **memory** for storing, among other things, identification information identifying a patient associated with the mouthpiece unit...
- ...the results of all measurements made using that mouthpiece unit 14 in the performance event **memory** 42 in association ...the portable base unit 12 from bed to bed in a hospital ward to collect **respiratory** data from a number of different patients each having his/her own mouthpiece unit 14...
- ...recorded in the hospital's records, each patient's data can be delivered to the **computer** ofhis/her personal physician.

In accordance with one embodiment of the present invention, the base unit \dots

...of the patient are recorded by the PPM 3 0 40 in the perfonnance event memory 42 along with corresponding time information.

As described above, the PPM 40 is also capable of querying the patient as to symptoms that are relevant to his **respiratory** condition. The patient's responses are then time tagged and stored within the performance event **memory** 42 for later analysis by the physician. For example, the PPM 40 can ask the...

- ...for example, at predetermined times of day, before and after medication use, or after a **respiratory** measurement has been made. In addition, the patient can input symptom information at any time...
 - ...base unit 12 and information contained within the signal is recorded within the performance event memory 42 with an appropriate time stamp. The wireless transceiver 44 then transmits an acknowledgment signal... back to Fig. 3, the electronics portion 66 of the circuit board 62 includes a memory I IO for use in storing information about the corresponding mouthpiece unit 14. The memory I 10 is preferably a non-volatile semiconductor memory (e.g., an EEPROM) that will not lose its contents during periods when little or no power is being I 0 supplied to the memory I 10 (such as when the mouthpiece unit 14 is detached from the base unit 12). In a preferred embodiment, the memory II 0 is used to store patient identification information identifying a patient having exclusive use...
 - ...the corresponding mouthpiece unit 14. The patient identification information will normally be stored in the **memory** I 10 by the physician when he assigns the corresponding mouthpiece unit 14 to 5...

...64 of the corresponding circuit board 62.

The calibration data can be stored in the memory I IO during manufacture and could be changed periodically as a result of re-calibrations.

The memory 1 1 0 is operatively connected to pins within the connector 68 to provide access...

- ...embodiment of the invention, the PPM 40 knows where particular information is stored within the **memory** I 1 0 and retrieves this information when the mouthpiece unit 14 is initially inserted...
- ...removed. The PPM 40, as discussed previously, uses the patient identification information retrieved from the memory I 10 to index the patient performance information stored in the performance event memory 42.

In situations where multiple patients are sharing a single base unit 12, this indexed...

...a patient currently using the base unit 12.

The sensor calibration information stored within the **memory** 1 1 0 will be retrieved by the measurement unit 3 8 when the mouthpiece...

...received from the sensors into meaningful measurement data.

In one embodiment of the invention, the **memory** 1 1 0 also stores **respiratory** performance information related to the corresponding patient. For example, the patient's personal best PEFR score can be stored in the **memory** I 10 for later comparison. The 1 5 PPM 40 can read this score from the **memory** II 0 and compare it to a current PEFR reading for the patient. If the...

- ...the personal best, the patient is congratulated and the previous personal best score within the **memory** 1 1 0 is replaced by the current score. If the current score is lower, the patient is informed of how much lower it is. The **memory** II 0 can also include information identifying the patient's physician (e.g., physician's...
- ...be used by the docking station 16, for example, to transfer a particular patient's **respiratory** -related information to the appropriate physician data collection station 18 (see Fig. 1).

With reference...

...the base unit 12. The cable assembly 1 16 allows a patient to perform a respiratory test from a position that is somewhat removed from the base unit 12. This additional...such as, for example, PEFR and FEVI levels. In one embodiment, a display of the respiratory maneuver can be provided. After these are displayed for a predetermined period offirme, other indications...mouthpiece unit 14 and store all subsequent test results corresponding to that patient within a memory inside the base unit 142, along with date and time information.

In a hospital environment...

...patient the results ofthe test. The data is subsequently transferred to an attending physician's **computer** 148 via, for example, hospital network 150 for use in 1 5 treating/monitoring the...

- ...he is in the hospital. The data can also be stored in the hospital's computer files on network 150 to maintain appropriate records for the patient. The stationary base unit...
- ...other information) already stored in the mouthpiece unit 14 to automatically and chronologically record all **respiratory** measurement results for the patient while he is in the hospital. In addition, the stationary...
- ...mouthpiece units 14, the hospital need not provide and program new mouthpieces for every new respiratory patient admitted to the hospital, resulting in significant cost savings for the hospital and the patient. Storage of physician identification information within the memory II 0 of the mouthpiece unit 14, as discussed previously, is especially advantageous in a...
- ...use physician identification information stored within a patient's mouthpiece unit 14 to transfer all **respiratory** -related data collected from the patient while in the hospital directly to the **computer** of the patient's personal physician (via, for example, the PSTN 152 or other public...

Claim

- ${\tt I}$. A method for obtaining information related to ${\tt respiratory}$ functions from
- a number of patients, comprising:
 providing a base unit;
- providing a first mouthpiece...
- ...processor and said first patient information includes first patient data related to at least one **respiratory** function of said first patient and said step of obtaining said first patient information includes...
- ...as claimed in Claim 4, wherein:
 - 3 0 said base unit includes a base unit memory and said first mouthpiece assembly includes a first mouthpiece memory and said step of obtaining said first patient information includes storing said first patient data correlated with said first patient identification information in said base unit memory.
 - 6 A method, as claimed in Claim 5, wherein: said step of obtaining said second patient information includes storing second patient data correlated with said second patient identification information in memory locations of said base unit memory previously having said first patient data correlated with said first patient identification information.

7 A...

- ...information and 1 5 then downloading said first patient identification information to a first mouthpiece memory of said first mouthpiece assembly using said docking station.

 9 . A method, as claimed in...
- ...by the first patient, information related to a first patient symptom into a base unit **memory** of said base unit.
 - 11 A method, as claimed in Claim IO, wherein:

said entering...

...base unit.

 $14\ \mbox{A}$ system for obtaining information from a number of patients related to

respiratory functions, comprising:

a base unit including a processor and a base unit $\ensuremath{\text{\textbf{memory}}}$ for storing patient

information;

- a first mouthpiece assembly that can be connected to said base unit and including a first mouthpiece **memory** that stores first patient identification information; and
- a second mouthpiece assembly that can be connected to said base unit and including a second mouthpiece **memory** that stores second patient identification
- 1 5 information;

wherein said processor is used to obtain said first patient identification information when said first mouthpiece memory is connected to said base unit and said processor is used to obtain said second patient identification information from said second mouthpiece memory when said second mouthpiece assembly is connected to said base unit.

- 15 A system, as memory .
- 19 A system, as claimed in Claim 14, further including:
 a cable assembly for use...
 ...said first mouthpiece assembly
 during a test.
 - 20 A system for obtaining information related to **respiratory** functions from at least one patient, comprising:
 - a mouthpiece assembly that includes a mouthpiece device...
- ...which the patient exhales, a flow board connected to said mouthpiece device, and a mouthpiece memory associated with said flow board that stores identification information for a first patient; a base...
- ...assembly and including a processor for reading said first patient identification information from said mouthpiece memory and a base unit memory for storing said first patient identification information with respiratory -related data from the first patient, with said processor correlating said patient data with said...
- ...as claimed in Claim 20, further including: a second mouthpiece assembly that includes a mouthpiece **memory** for storing identification information for a second patient different from the first patient and in...
- ...second mouthpiece assembly is joined to said base unit after said first mouthpiece assembly is **removed** therefrom.
 - 22 A ${\tt system}$, as claimed in Claim 20, further including, a docking station in communication with said mouthpiece assembly for use in downloading said first patient identification information to said mouthpiece ${\tt memory}$.
 - 23 A system, as claimed in Claim 20, wherein:

said base unit includes a display...

:A OR V

...I O said base unit includes means for controlling a storing in said base unit memory of first patient data related to exhalation by the first patient using said mouthpiece assembly... ...distal connectors. 27 A system for obtaining information from at least one patient related respiratory functions, comprising: a mouthpiece assembly including a mouthpiece device into which a patient . exhales; a... ...operatively connected to said mouthpiece assembly and including a processor for processing patient data, a memory for storing patient data, and a display for displaying at least patient instructions; and a... ...28 A system, as claimed in Claim 27, wherein: said mouthpiece assembly includes a mouthpiece memory for storing patient identification information. 29 A system, as claimed in Claim 27, wherein: said... ...LCD DISPLAY 50 WIRELESS 40 52 TRANSCEIVER KEYPAD PATIENT PERFORMANCE MANAGER PERFORMANCE SPEAKER 54 EVENT **MEMORY** 48 56: f CROPHONE VOICE VOICE SYNTHESIS RECOGNITION FIGO 2 /10 64 70 60 66...CUSTOM SYMPTOM =4 BEST PATIENT GUESS PRESS E TO EDIT" 0-999 FOR BLOW VIA PC AORV "PRESS E "10/3010:33:12 CE RESULTS" DYSPNEA = 5"

32/3,K/172 (Item 172 from file: 349) DIALOG(R) File 349: PCT FULLTEXT (c) 2004 WIPO/Univentio. All rts. reserv. **Image available** VENTILATOR CONTROL SYSTEM AND METHOD SYSTEME ET PROCEDE DE COMMANDE D'UN VENTILATEUR Patent Applicant/Assignee: CARDIOPULMONARY CORPORATION, Inventor(s): BIONDI James W, JOHNSTON Douglas M, SCHROEDER Gerhardt P, GILMORE Donald D, REYNOLDS Robert, = (US) 6188 43C Patent and Priority Information (Country, Number, Date): WO 9947200 Al 19990923 Application: WO 99US6056 19990319 (PCT/WO US9906056) Priority Application: US 9845461 19980320 Designated States: (Protection type is "patent" unless otherwise stated - for application prior to 2004) IL AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE Publication Language: English Fulltext Word Count: 12115 VENTILATOR CONTROL SYSTEM AND METHOD Main International Patent Class: A61M-016/00 Fulltext Availability:

English Abstract

Claims

Detailed Description

...exhalation assist device for adjusting the airway resistance in an exhalation circuit of a medical **ventilator** (17). The **device** includes a set of pressure, airflow and airway sensors (7, 11, 9), a controlling processor, a **user interface** (24, 26), and a **ventilatory** unit in communication with a medical **ventilator** (17). Data relating to pressure within the **ventilatory** unit and data relating to exhalation airflow, exhalation circuit pressure and exhalation circuit resistance are...

...signal that will change the applied negative pressure applied to the exhalation circuit by the **ventilatory** unit. The amount of negative pressure applied during the breathing cycle is varied by the...

...the patient airway (21) remains constant at a level greater than zero and less than ${\tt PEEP}$. French Abstract

 \ldots un niveau superieur a zero et inferieur a la pression positive en fin d'expiration (<code>PEEP</code>).

Detailed Description

Ventilator Control System and Method

Field of the Invention

The invention relates generally to the field of **respiratory** assist **devices** such as **ventilators**. In particular, the invention relates to a **ventilator** control system and method for controlling a **ventilator** pneumatic system.

Background of the Invention
A medical ventilator delivers gas to a patient's respiratory tract

and is often required when the patient is unable to maintain adequate **ventilation**. **Mechanical ventilation** is the single most important therapeutic modality in the care of critically ill patients. Known **ventilators** typically include a pneumatic system that delivers and extracts gas pressure, flow and volume characteristics...

...as the condition of the patient changes. Such adjustments, although highly desirable, are difficult to implement with known ventilators because the control system demands continuous 1 5 attention and interaction from the clinician.

Further, patients requiring **ventilatory** assistance must overcome airway resistance in the breathing circuit during exhalation. This resistance, combined with...

...breathin without compromising patient ventilation requirements.

SummM of the Invention

The invention relates to a **ventilatory** assist **device** that decreases the resistance to exhalation in the exhalation circuit of a medical **ventilator**. The **device** adjusts the resistance within the exhalation circuit by generating a negative pressure around a gas...

- ...relating to airway pressure, airway resistance or applied negative pressure through a control panel. A microprocessor within the data processing unit of the device compares these values with data for airway pressure, airway resistance and applied negative pressure that have been measured or calculated by sensors within the device. The microprocessor then adjusts the amount of negative pressure to be created within the gas exchange 1...
- ...regulates the flow through the Venturi valve in response to signals it receives from the microprocessor within the data processing unit that calculates the amount by which the applied negative pressure is to be changed. A pressure sensor in communication with the ventilatory unit measures the negative pressure applied to the gas exchange reservoir and transmits these data to the data processing unit.

A method of exhalation assist compensates for resistance to gas flow encountered by a patient...

...circuit so as to alter the measured values to reach the desired values.

The term " ventilator control setting structure" is defined as a collection of information sufficient to control one parameter...

- ...The term Cccycle control structure" is defined as a collection of waveforin samples and a **ventilator** control setting Structure for each parameter. The term "phase control structure" is defined as a collection of phase switching rules that defines how the **ventilator** control settings are to be utilized and a **ventilator** control setting for each controllable parameter that exists in the **ventilator**. Each phase has one or more triggers that are tested every cycle (4 Msecs per cycle) to decide which **ventilator** control setting to use.
 - I 0
 The term "breath control structure" is defined as a collection of phase switching rules that defines how and when one **ventilatory** breath phase is to switch to another **ventilatory** breath phase and a phase control structure for each phase of breath defined by the specified breath.

Breath phases break up a **ventilatory** breath into as many phases as desired in order to control 1 5 inspiration, pause, expiration assist and **PEEP** with any desired level of control for the specified breath. Each breath has one or...

- ...is defined as a collection of breath switching rules that defines how and when one **ventilatory** breath is to switch to another **ventilatory** breath and a breath control structure for each type of breath defined by the specified...in the accompanying drawings.
 - FIG. I is a block diagram of an embodiment of a **ventilator** of the invention.
 - FIG. 2 is a detailed block diagram of a display controller. FIG...
- ...block diagram of an embedded controller.
 - FIG. 4 is a detailed block diagram of a ventilator pneumatic unit.
 - FIG. 5 is a diagram illustrating an embodiment of the adjustment of negative...
- ...determine patient ventilation triggering.
 - FIG. 7 is an illustration of a display screen when the **ventilator** control system is in the operational mode.
 - FIG. 8 is an illustration of a section...
- ...FIG. I IO is a flow chart of the data structure hierarchy employed by the **ventilator** control system.
 - FIG. 12 is an embodiment of a flow chart of an exhalation assist...
- ...the invention.
 - FIG. 13 is an illustration of a simulation mode display screen for the **ventilator** control system.
 - FIG. 14 is a functional block diagram of the simulator portion of the ventilator
 - control system
 - FIG. 15 is an illustration of a section of the display screening showing a waveform shaper.
 - FIG. 16 is an illustration of a therapy programming screen for the **ventilator** control system.

Detailed Descriptio

- 1. Ventilator Control System The invention features a ventilator control system for controlling a ventilator pneumatic system in a medical ventilator. The ventilator control system provides a clinician with complete control of a patient's airway flow and pressure throughout the respiratory cycle, and thereby enables the clinician to determine the optimal therapy for the patient. In...
- ...this situation, negative pressure can be applied to the exhalation circuit of the patient's **ventilator** to reduce the resistance to airflow.

I 0 Because resistance to airflow is an exponential...be averted.

If airway pressure rises above the clinically indicated level of positive endexpiratory pressure (PEEP), the lung will be overpressurized thus the effective airway pressure throughout the expiratory cycle is fitrated throughout the expiratory phase under precise algorithmic control. The clinical benefit of a certain PEEP level will be diminished.

Thus, the effective airway pressure throughout the expiratory cycle must remain greater than zero and less than ${\tt PEEP}$.

- FIG. I is a block diagram of a **ventilator** including a **ventilator** control system IO incorporating the features of the invention. The **ventilator** control system 10 includes a display controller 12 and an embedded controller 14. The display...
- ...interface to the clinician 16, and the embedded controller 14 provides an interface with a **ventilator** 17 providing ventilation to a patient 20. The display controller 12 and the embedded controller 14 each include **memory** (not shown) and are electrically coupled via a shared **memory** interface 15. Data from the display controller 12 and the embedded controller 14 are stored...
- ...embedded controller 14 to calculate the amount of negative pressure to be generated in the **ventilator** 17 in order to produce an airway pressure greater than zero and less than positive...
- ...gas delivered from the source of pressurized gas 45 through a Venturi valve within the **ventilator** 17 to produce this negative pressure. One I 0 embodiment of such a pneumatic system...
- ...by reference. A pressure sensor 51 measures the amount of negative pressure produced within the **ventilator** 17 and transmits these data to the embedded controller 14. These data are stored in...
- ...controller 12. Each of these target values is compared with a corresponding current value of **ventilatory** unit pressure, airway pressure, airway flow and air-way resistance by the embedded controller 14 changes the amount of negative pressure produced by the **ventilator** 17. The **ventilator** 17 is in pneumatic communication with a flexible tubing 21 capable of attachment to a...
- ...application, serial number 08/352,658, incorporated herein by reference.

The safe performance of the **ventilator** I 0 is enhanced by the redundancy of the two independent display controller 22 and embedded controller 30 processors, which continually check each other's performance via the shared **memory** interface 15. The embedded controller 14 communicates its status, and that of the patient, to...

- ...the last known good settings if communication becomes lost. The two systems which comprise the **ventilator** control system IO give both audible and visual messages when an alarm condition exists, and...
- ...absence of breathing). During operation, both systems perform background tests to detect system faults. The **ventilator** provides a series of reduced operation modes to provide life support if system capability is ...highly flexible means to change control settings.

The display controller 12 is a powerful graphics workstation with hardware and I 0 software components. In one embodiment, the clinician

interacts with the...

...to the monitor. In one embodiment, the processor 22 is included in a single board **computer** which also includes **RAM**, an integrated high speed graphics 1 5 driver, and an integrated dual port **memory**. The display controller 12 also includes a hard disk drive 23.

While the display controller 12 provides interpretation and decision support information on the display 24, the **ventilator** 17 does not change any breath control parameters unless directed by the clinician 16. Nevertheless, the display controller 12 provides a flexible **user** interface with multiple interactive levels, from simple text menus of controls for inexperienced users, to complete...

- ...embedded controller 14 includes a system board 28, a real time data processor 30, a ventilator processor 32 and an air-way processor31. Therealtimeprocessor30managessensordatacollectionfromthesensor monitoring system 19, processes measured data, performs alarm/fault detection and provides control data to the ventilator 17. The embedded controller 14 further receives data input by the clinician 16 and accesses...
- ...system 19 relating to airway pressure, flow and resistance. A second data processor 32, a **ventilatory** unit processor, receives signals from the pressure sensor 51 in communication with the **ventilatory** pneumatic system 18. Signals from both data processors 31 and 32 are transmitted to a...to airway pressure, flow and resistance to preselected values and then calculating the change in **ventilatory** unit negative pressure required to affect the desired change in airway resistance.

In more detail, and referring also to FIG. 4, a block diagram of the **ventilator** 17 in communication with the flexible airway 21 that is the conduit for inhalation from...

...airway 21 to assist the patient's exhalation through the canister 49 into the medical **ventilator** 7.

Pressure within the flexible canister 49 is measured by a pressure sensor 5 $1\dots$

...controller 14.

Now referring also to FIG. 5 a detailed functional block diagram of the **ventilator** control system 10 is depicted. As shown, the clinician 16 manipulates a control setting slider...

- ...the clinician's inputs and creating 40 a breath control structure which is stored in **memory** . The display I 0 controller 12 transmits the breath control structure to the embedded controller...
- ...panel 36. The embedded controller 14 initially stores 44 the breath control structure in local **memory** .

The embdded controller 14 re-validates 46 the settings within the breath control structure.

The embedded controller 14 implements 48 the validated breath control structure 48 using a breath control algorithm 50 and provides signals to the pneumatic...panel 3 6 to the cause of the error and the process is terminated.

The **ventilator** control system 10 provides two independent feedback paths to assure the clinician 16 that his...

- ...displays 60 a series of measurements (e.g., peak airway pressure, peak airway flow, and **PEEP**) from the waveform data both numerically and graphically, Second, the display controller 12 displays 54...
- ...the embedded controller 14 and passed directly to the display 24.

 One feature of the **ventilator** control system IO is that it can be configured to provide an assisted phase of...
- ...the accumulated volume of gas inhaled by the patient as a result of his spontaneous **respiratory** muscle activity can be monitored. To accomplish this 7the sensor monitoring system 19 measures the...
- ...volume dynamically according to measured patient flow and pressure signals indicating the phase of the **respiratory** cycle.

In particular, the embedded controller 14 may increase the trigger volume set by the...

...system 4 1, and not by spontaneous efforts of the patient.

Another feature of the **ventilator** control system is its ability to distinguish between active inspiratory effort and passive reverse airflow ...measured until the trigger volume has been reached (Steps 320, 330).

- Another feature of the **ventilator** control system is its ability to compensate for gas flow resistance into and out of...
- ...input device 26, the clinician 16 can set a resistance parameter of the patient's **respiratory** system to a selected value. Alternatively, the display controller 12 may calculate a value for...
- ...row of touch sensitive on/off buttons 66 includes: a Power button that controls the **ventilator** control system— a Freeze button to pause the display— a Modes button to display various...
- ...play back a database of historical patient protocols; a 100% 02 button to flush the **ventilator** with oxygen; Help and Save buttons; and ... other capabilities.

The left side of the screen includes a list of the publically available ventilator control settings. The top area displays the current mode of ventilation 67 (e.g., Backup...and partially controlled by the patient, and mandatory breaths, those triggered and controlled by the ventilator. The ratio of the colored areas indicates the ratio of spontaneous to mandatory breathing during...

...When the clinician selects a phase of a waveform, the display controller displays the associated **ventilator** controls for available for adjustment by the clinician.

The display controller provides cursors 201 which waveform values, positioning based on **user interface** gestures.

The background of the waveform (74, 76) includes color shading to indicate breath phase...

...and scale information. Redrawing these graphics as new waveform samples are displayed generally requires substantial **computer** time, and the display controller performs this function efficiently notwithstanding the

complexity of the background...Inspiratory Pressure 2 to 120 cmH20 Exhalation Assist 0 to 30 cmH?O/L/sec

PEEP 0 to 20 cmH20
Inspiratory Time 0.2 to 4 sec
Inspiratory Pause Time 0...

...L/min

Oxygen Percentage 21 to 100%
Peak Inspiratory Pressure 0 to 120 cm.H20
PEEP 0 to 20 cmH,)0
Mean Airway Pressure 0 to 120 cmH20
Inspiratory Time 0...
...and Indicators
I-Egh/Low Exhaled Tidal Volume Alarm 50 to 2000 ml,

I-Egh/Low Exhaled Tidal Volume Alarm 50 to 2000 ml FEgh/Low Respiratory Rate Alarm 2 to 150 bpm Low Oxygen Fresh Gas Flow Automatic, % 02 depend

Low...Embedded Controller - Referring again to Fig. 1, the embedded controller electronics 14 is based around microprocessors 31, 32. The microprocessor 32 is in electrical communication-with the ventilatory unit 17 and the microprocessor 31 is in electrical communication with the sensor monitoring system 19. The embedded controller relies...

- ...custom printed circuit boards to perform other functions. The modules, the printed circuit boards, the **ventilatory** unit pressure processors 32 and the airway processor 31 are mounted on or connected to...
- ...and provides battery backup for a average of one hour.

The embedded controller 14 has **microprocessor** and associated input/output hardware to provide for closed loop control of pneumatic system 41...Third Gas.

The embedded controller 14 communicates with the display controller 12 via a shared **memory** interface 15 at a data transmission rate exceeding I OOK bytes per second.

4. Data...

- ...to FIGS. I and I 1, the figures illustrate the data structure hierarchy for the **ventilator** control system. Using an input device 26 such as the touch-sensitive display 24 within...
- ...13. In any case, the clinician 16 sends the new therapy control structure to the **memory** for use by the embedded controller 14 in controlling the pneumatic system 4 1. A control) is defined as a collection of **ventilator** control settings 154 and an array of waveform samples 156. Phase definitions and requirements for...
- ...to measurable system performance, and correlate closely to published descriptions of the desired behavior of $\mbox{mechanical}$ $\mbox{ventilators}$.

More specifically, the therapy control structure 140 is a nested hierarchy of increasingly complex control...

...control, which occurs within therapy control, which is the clinically specified therapy that drives the **ventilator** pneumatic system 4 1. Once each cycle, ventilation control moves from one control state to assist phase to a **PEEP** phase, but these phases may be further subdivided for a finer granularity of control.

After...

- ...Within a phase, within a breath, within a mode, within a therapy, there is a **ventilator** control setting structure 154. This structure contains an array of samples that comprise a specified...
- ...is driven by the waveform sample specific for the cycle, and by a collection of **ventilator** control settings 154 specific for the phase. The cycle time is in milliseconds, and is...
- ...therapy may be specified by the clinician and take control at the next cycle.

Each ventilator control setting structure 158 contains necessary and sufficient information to control one parameter of ventilation...

...adjusted automatically within the specified range. Each phase control structure has its own collection of **ventilator** control settings, although in practice, phases within a breath generally share the same collection.

The...

...of hazardous conditions by permitting non-programmers to review and understand the function of the **ventilator** control system.

Several breath control structures are predefined in the embedded controller. These breath control relating to airway resistance or negative pressure in the **ventilatory** unit (Step 1). These values are then compared with data relating to airway - 24 resistance or negative pressure in the **ventilatory** unit that have been measured or calculated by the **data processing unit** (Step 2). It is then determined whether these sets of data are equal to each...

- ...7). It is then determined whether airway pressure is greater than zero and less than PEEP (Step 8). If airway pressure is greater than zero and less than PEEP, airway resistance is calculated and pressure in the ventilatory unit is measured (Step 9). After these measurements and calculations are made, the cycle recommences (Step 2). If airway 5 pressure is not greater than zero and less than PEEP, it is determined whether the alarm has been overridden (Step IO). If the alarm has...
- ...status of the patient's pulmonary system. The simulator 212 simulates the adjustment to the **ventilator** pneumatic system 41 in response to the set of breath parameters and the response of...

...is unaffected.

- 25 When the clinician 16 begins changing settings in the simulation mode, the **ventilator** control system IO predicts the effects of the change and displays the predicted result on the display 24. The simulator 212 uses a standard two parameter model of a **respiratory** system and the current calculated values of the patient's resistance and compliance to predict the effect. The model assumes no contribution from the patient's **respiratory** muscles (i.e., a passive inspiration and exhalation cycle). The model used is.

Airway Pressure...

- ...Compliance)
 - + (Airway Flow x Airway Resistance).
 - I 0 A change in patient intervention in current **ventilators** typically requires multiple setting changes. Implementing such setting changes is greatly complicated by the series...
- ...background. Other controls are listed as active or inactive. The explicit list of active controls clearly delineates the exact function of the mode and alleviates confusion caused by inconsistent or incomplete definitions. Moreover, the simulator 212 can precisely replicate the behavior of modes on preexisting ventilators.

The clinician 16 can make adjustments to the list of controls to accurately simulate the **ventilator** that a hospital's staff has been trained to use. The list of controls together...

...simulated behavior can help teach the effects of various modes on patients, rather than the **ventilator** -specific mode definition.

As claimed in FIG. 13, while the simulator 212 predicts the shape...a touch zone on the display 24. The processor 22copies the selected patient protocol into **memory**. In the operational mode, the processor 22 instructs the embedded controller 14 1 5 to...

...selected patient protocol. In the simulation mode, the simulator 212 simulates the adjustment to the **ventilator** pneumatic system 41 and the resulting response of the patient's pulmonary system.

The processor...

...expected.

FIG. 14 is a detailed functional block diagram of the simulator feature of the **ventilator** control system 2 1 0. The clinician manipulates a control setting slider 216 to 3 0 change or set a **ventilator** control setting. The clinician's input are stored in a **memory** - 27 218. The simulator 220 receives the inputs and creates a phase control structure, a...

- ...a therapy control structure) is transmitted to the embedded controller (at 224) via the shared **memory** interface. The embedded controller validates the settings within the breath control structure 226. The processor...data stream can be generated by sensors, which is the usual manner in which the **ventilator** operates, by the simulator 212 which uses the breath parameters and measured patient parameters to...
 ...to display real data, simulated data and epoch data is an important feature of the **ventilator** control system.
 - 28 9. Integrated Control/Data/Alarni Display Referring again to FIG. 7, patient...selected targets appropriate for the range, and which, if enabled, 1 5 means that the **ventilator** control system will seek to accomplish a range target goal 213 by varying the control...the trigger for the transition from variable pressure support (VPS) to assist control (A/C **pc**) is minute volume (MV), while the trigger for the 30 transition from assist control to...
- ...the patient, with much more power and flexibility than selecting from a set of simple **ventilator** modes preset by the manufacturer.

Equivalents

1 5 While the invention has been particularly shown...

Claim

- I 1. A method of compensating for the gas flow resistance in a **ventilatory** apparatus, the method comprising the steps of: determining the peak exhalation flow rate; determining the airway...
- \dots exhalation circuit such that the effective circuit pressure is greater than zero and less than ${\tt PEEP}$.
 - 2 A method of claim 1, further comprising adjusting the amount of negative pressure to generate a predetermined effective circuit pressure with a measured value between zero and PEEP.
 - $3\ \text{A}$ method of claim I further comprising measuring an exhaled tidal volume and adjusting...
- ...said instantaneous changes
 with predetermined parameters; and
 storing these data in a database.
 5 A ventilator assist device comprising:
 a reservoir for inhaled and exhaled gas in communication with a
 breathing apparatus adapted for attachment to a patient'.
 a source of negative pressure in communication with said reservoir;
 32 a data processing unit in electrical communication with said
 negative pressure source and also in electrical communication with an...
- ...circuit resistance sensor; said exhalation flowmeter and said circuit resistance sensor in communication with said breathing apparatus; and a user interface in electrical communication with said negative pressure source allowing direct setting of a value for desired negative airway pressure by a user.
 - 6 The ventilator assist device of claim 5 further comprising: a flexible canister attached to gas inflow and outflow circuits of a ventilator in pneumatic communication with the exhalation circuit adapted for connection to the patient being ventilated...2 1 generated in said airway tubing that is greater than zero and less than PEEP.
 - 7 The controlling processor of claim 6 further comprising:
 - a first data processor in electrical...
- ...applied to generate a pressure in said airway tubing greater than zero and less than PEEP; said third data processor further calculating from the data input from said exhalation flowmeter and...
- ...first, second and third data processors, 1 5 wherein said database is adapted for storing data processed by said first, second and third data processors.
 - 8 The user interface of claim 5 further comprising: a display screen and the control panel, whereby said display...
- ...controls;
 - said plurality of controls in electrical communication with the gas flow controller; and said user interface in electrical communication with the database, with the third data processor and with the gas...

...comprising:

an alarm system in electrical communication with the third data processor and with the user interface that is triggered by a level of pressure in said airway tubing less than zero or greater than PEEP; and

an override device in electrical communication with said alarm system and with said user interface that discontinues the alarm signal in response to a command input by the user. I...

```
Items
                 Description
S1
       147107
                 (VENTILAT? OR RESPIRAT? OR BREATH?) (3N) (DEVICE? OR UTENSIL?
              OR APPARAT? OR TOOL? OR IMPLEMENT? OR INSTRUMENT? OR APPLIAN-
             C? OR EQUIPMENT? OR MACHINE? OR MECHANIC?)
S2
                 VENTILATOR? OR VENTILATER? OR RESPIRATOR? OR RESPIRATER? OR
              HFV OR IMV OR IPAP OR CPAV OR PEEP OR CPAP
S3
      7895338
                 CLEAR? OR CANCEL? OR ERASE? OR ERASUR? OR ERASING? OR DELE-
             T? OR OVERRID? OR OVERWRIT? OR OVER() (RIDE? OR RIDING OR WRIT-
              ?) OR REPROGRAM? OR REMOV? OR RESET? OR MODIF?
S4
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S5
      5459410
                 PERFORMANC? OR WORKING? OR EXECUTI?
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S6
                 DATA? OR PROGRAM?
S7
       859354
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       103624
S8
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S9
        30904
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             OR MEMORY) (3N) CARD? OR SMARTCARD? OR CHIPCARD?
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S10
       291441
             ELECTRONIC? OR OPTIC? OR MAGNET?) OR USER?()INTERFACE?
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S11
             CHABL? OR STANDALONE OR STAND() ALONE OR PORTABL OR INSERTABL?-
              )(2N)(UNIT? OR DEVICE?)
                 CPU OR CPUS OR PROGRAM? () CONTROL? OR PROCESS? (2N) CONTROL? -
S12
      1050617
             OR MICROPROCESS? OR DATAPROCESS? OR CENTRALPROCESS? OR (MICRO
             OR DATA OR CENTRAL) () PROCESS?
S13
                 PROCESS?()UNIT? OR WORKSTATION? OR WORK()STATION? OR DESKT-
             OP? OR DESK() (TOP OR TOPS) OR SERVER?
S14
      5992536
                 COMPUTER OR COMPUTERS OR PC OR PCS
S15
     18204098
                METHOD? ?
S16
          712
                 S1:S2 AND S9:S11 AND S12:S14
S17
           16
                 S16 AND S3(5N)(S4:S14)
S18
           94
                 S16 AND S3
S19
           94
                 S17:S18
S20
           33
                 S19 AND S15
S21
           94
                 S19:S20
·S22
           72
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              OR APPARAT? OR TOOL? OR IMPLEMENT? OR INSTRUMENT? OR APPLIAN-
             C? OR EQUIPMENT? OR MACHINE? OR MECHANIC?)
S2
       179677
                VENTILATOR? OR VENTILATER? OR RESPIRATOR? OR RESPIRATER? OR
              HFV OR IMV OR IPAP OR CPAV OR PEEP OR CPAP
S3
      4825840
                CLEAR? OR CANCEL? OR ERASE? OR ERASUR? OR ERASING? OR DELE-
             T? OR OVERRID? OR OVERWRIT? OR OVER() (RIDE? OR RIDING OR WRIT-
             ?) OR REPROGRAM? OR REMOV? OR RESET? OR MODIF?
S4
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                OPERAT? OR FUNCTION?
S5
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S6
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                 DATA? OR PROGRAM?
S7
      4094086
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S8
       212009
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S9
       246586
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S10
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S11
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             CHABL? OR STANDALONE OR STAND() ALONE OR PORTABL OR INSERTABL?-
             )(2N)(UNIT? OR DEVICE?)
S12
      1002468
                CPU OR CPUS OR PROGRAM? () CONTROL? OR PROCESS? (2N) CONTROL? -
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             OR DATA OR CENTRAL) () PROCESS?
S13
                PROCESS?()UNIT? OR WORKSTATION? OR WORK()STATION? OR DESKT-
             OP? OR DESK() (TOP OR TOPS) OR SERVER?
                COMPUTER OR COMPUTERS OR PC OR PCS
S14
      6925033
S15
      1693714
                METHOD? ?
S16
      5051036
                PROCESS??
S17
      1865108
                PROCEDUR?
S18
      2776819
                MODE? ?
S19
         3225
                S1:S2 AND S9:S11 AND S12:S14
S20
          587
                S19 AND S3(5N)S4:S14
S21
           39
                S20 AND S1:S2(5N)S9:S14
S22
           28
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